From: Druwe, Ingrid [Druwe.Ingrid@epa.gov]

Sent: 12/14/2017 6:21:27 PM

To: Druwe, Ingrid [Druwe.Ingrid@epa.gov]; drsg-l@indiana.edu

CC: Beck, Nancy [Beck.Nancy@epa.gov]; Davis, Allen [Davis.Allen@epa.gov]; Rick Reiss [rreiss@exponent.com]; Musso,

Michael P. [Michael.Musso@hdrinc.com]; Lowney, Carrie A [carrie.a.lowney@zoetis.com]; Ian Collins

[Ian.Collins@ghd.com]; Blessinger, Todd [blessinger.todd@epa.gov]; Wayne Landis [Wayne.Landis@wwu.edu]; Dalaijamts, Chimeddulam [CDalaijamts@cvm.tamu.edu]; Lorenz Rhomberg [Irhomberg@gradientcorp.com]; Mary

Jane Calvey [mjcalvey@rwmsinc.com]; Woodall, George [Woodall.George@epa.gov]; Setzer, Woodrow

[Setzer.Woodrow@epa.gov]; Chiu, Weihsueh [WChiu@cvm.tamu.edu]; Flowers, Lynn [Flowers.Lynn@epa.gov];

Schlosser, Paul [Schlosser.Paul@epa.gov]; Jarabek, Annie [Jarabek.Annie@epa.gov]; Berner, Ted [Berner.Ted@epa.gov]; Bette Meek [bmeek@uottawa.ca]; Gibson, Jacqueline MacDonald [jackie.macdonald@unc.edu]; Philip Goodrum [pgoodrum@integral-corp.com]; Kenneth Bogen [kbogen@exponent.com]; xly@bnu.edu.cn; Yeager, Raymond (Phil) [Raymond.Yeager@fda.hhs.gov]; riesd@michigan.gov [RIESD@michigan.gov]; Robinan Gentry [rgentry@ramboll.com]; Petersen, Dan

[Petersen.Dan@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Putzrath, Resha M CIV USN NAVMCPUBHLTHCEN PORS (US) [resha.m.putzrath.civ@mail.mil]; Wright, Michael [Wright.Michael@epa.gov]; Kopylev, Leonid [Kopylev.Leonid@epa.gov]; Swartout, Jeffrey [swartout.jeff@epa.gov];

Young, Melanie [Young.Melanie@epa.gov]; Farrar, David [Farrar.David@epa.gov]; Simmons, Jane [Simmons.Jane@epa.gov]; Gift, Jeff [Gift.Jeff@epa.gov]; Theodore, Shaji [Shaji.Theodore@fda.hhs.gov];

Rick_Becker@americanchemistry.com

Subject: Reminder: DRSG Monthly Meeting Today

Location: Teleconference: Conference Line/Code / Ex. 6

Start: 1/9/2018 5:00:00 PM **End**: 1/9/2018 6:00:00 PM

Show Time As: Tentative

Proposed ideas for symposia:

- Dose Response and Law
- Success of DR
- Systematic review and DR
- Machine Learning & SR-Translate science to decision (jackie volunteered for this one)
- New data for use in DR; how to communicate data → Segway to symposia
- Attention to how to properly design experiments to inform DR
- Scott Auerbach- BMD Express-NIH version
- How to facilitate open data dose response health benefits- Dan Kruskie of Iowa (CatReg?); Neal Fann OAQPS
 BenMap

Moving meeting to 2nd Tuesday in January to accommodate travel & holiday schedules. Please make note of new Adobe connect & web conferencing information

Call-in number(s) and access code(s)

Teleconference: Adobe Connect:

Conference Line/Code / Ex. 6

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]

Sent: 1/12/2018 9:50:07 PM

To: Beck, Nancy [beck.nancy@epa.gov]; Deziel, Dennis (DR) [DRDeziel@dow.com]

Subject: General

Location: Elephant and Castle

Start: 1/19/2018 5:15:00 PM **End**: 1/19/2018 6:30:00 PM

Show Time As: Busy

From: Thomas M. Connelly [T_Connelly@acs.org]

Sent: 5/24/2017 8:46:13 PM

To: Thomas M. Connelly [T_Connelly@acs.org]; m_kirchhoff@acs.org; Beck, Nancy [beck.nancy@epa.gov]

Subject: 5:15 p.m. Nancy Beck, Deputy Assistant, OCSP

Location: 202-564-1273 Tom to Call Mrs. Nancy Beck directly/Tom's Office

Start: 5/24/2017 9:15:00 PM **End**: 5/24/2017 9:45:00 PM

Show Time As: Tentative

Recurrence: (none)

SRS

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, May 22, 2017 12:37 PM **To:** Simanco Staley <<u>S Staley@acs.org</u>> **Subject:** RE: Call w/ Mrs. Beck next week?

Yes, that works. P: 202-564-1273

Can you please send a calendar invite so I don't forget about it?

Thanks!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Simanco Staley [mailto:S_Staley@acs.org]

Sent: Monday, May 22, 2017 12:29 PM
To: Beck, Nancy < Beck. Nancy @epa.gov>

Cc: Milhouse, Gloria < Milhouse. Gloria@epa.gov>

Subject: RE: Call w/ Mrs. Beck next week?

5:00 p.m. would work better; can you do that? If so, what number would be best for him to call you on?

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, May 22, 2017 12:15 PM

To: Simanco Staley < S Staley@acs.org>; Milhouse, Gloria < Milhouse. Gloria@epa.gov>

Subject: RE: Call w/ Mrs. Beck next week?

Hows about 4:30 this Wednesday?

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Simanco Staley [mailto:S_Staley@acs.org]

Sent: Friday, May 19, 2017 11:01 AM

To: Milhouse, Gloria < Milhouse, Gloria@epa.gov>

Cc: Beck, Nancy <<u>Beck.Nancy@epa.gov</u>> **Subject:** RE: Call w/ Mrs. Beck next week?

Good Morning Gloria,

Any luck with any of these dates/times?

Sincerely,

Simanco

From: Simanco Staley

Sent: Wednesday, May 17, 2017 1:21 PM

To: 'milhouse.gloria@epa.gov' <milhouse.gloria@epa.gov>

Subject: Call w/ Mrs. Beck next week?

Importance: High

Good Afternoon Gloria,

Thanks so much for your willingness to help me set up a call with Mrs. Beck to discuss the Green Chemistry Challenge Awards.

Would any of these dates/times work for a 30 minute call?

Monday, May 22^{nd} 11:30 a.m. - 12:00 p.m. or after 4:00 p.m. Tuesday, May 23^{rd} 9:30 - 10:00 a.m. or after 4:00 p.m. Wednesday, May 24^{th} 8:00 - 9:30 a.m. or after 4:00 p.m. Thursday, May 25^{th} after 2:30 p.m.

Please let me know. Thanks in advance and I look forward to hearing from you soon.

Sincerely,

Simanco

Simanco Staley
Senior Executive Assistant to the Executive Director and Chief Executive Officer
American Chemical Society
1155 16th Street NW
Washington, D.C. 20036
Phone: (202) 872-6010

Phone: (202) 872-6019 Fax: (202) 872-6055

The ACS Vision: Improving people's lives through the transforming power of chemistry

ACS Chemistry for Life

American Chemical Society www.acs.org

From: Marshall, Venus [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBD81A18F6AD447F90B8ABBCB90FE9DB-VENUS ASHTON]

Sent: 7/25/2017 2:42:20 PM

To: Beck, Nancy [beck.nancy@epa.gov]; sara.e.hopper@dupont.com

BCC: DCRoomEast3156/DC-EPA-EAST-OCSPP [DCRoomEast3156@epa.gov]

Subject: ESA/FIFRA Issue (confirmed)
Attachments: Read: [EXTERNAL] ESA/FIFRA Issue

Location: RM 3156 EPA East

Start: 8/18/2017 8:15:00 PM **End**: 8/18/2017 8:45:00 PM

Show Time As: Busy

Purpose/Subject: To discuss Section 5 (e) Review Process

Location Address: 1201 Constitution Avenue, NW - Washington, DC

Please have the guards call 202-564-2910 or 202-564-2902 for an escort.

From: Thomas M. Connelly [T_Connelly@acs.org]

Sent: 4/16/2018 9:33:13 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: Green Chemistry Challenge Award Program

Nancy,

Thanks for your speedy reply. It has been a very valuable program. We will fill the gap this year, but keep you in the loop. With hope, we can pursue this in partnership again next year.

All best wishes, Tom

Thomas M. Connelly, PhD.
Executive Director and Chief Executive Officer
American Chemical Society
1155 16th Street NW
Washington, D.C. 20036

Phone: (202) 872-4466 Fax: (202) 872-6055

The ACS Vision: Improving people's lives through the transforming power of chemistry

ACS Chemistry for Life American Chemical Society

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, April 16, 2018 2:30 PM

To: Thomas M. Connelly <T_Connelly@acs.org>

Cc: Morris, Jeff < Morris.Jeff@epa.gov>

Subject: RE: Green Chemistry Challenge Award Program

Tom,

Thank you for your letter. Its great news that ACS can fill the gap in 2018 by continuing to provide green chemistry awards.

Regards, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Thomas M. Connelly [mailto:T_Connelly@acs.org]

Sent: Friday, April 13, 2018 12:48 PM **To:** Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Thomas M. Connelly <<u>T_Connelly@acs.org</u>>; Morris, Jeff <<u>Morris.Jeff@epa.gov</u>>

Subject: Green Chemistry Challenge Award Program

Importance: High

Good Afternoon Nancy,

Please see attached letter.

Sincerely yours,

Tom

Thomas M. Connelly, PhD.
Executive Director and Chief Executive Officer
American Chemical Society
1155 16th Street NW
Washington, D.C. 20036
Phone: (200) 872, 4466

Phone: (202) 872-4466 Fax: (202) 872-6055

The ACS Vision: Improving people's lives through the transforming power of chemistry

ACS Chemistry for Life American Chemical Society

From: kathy.plotzke@dowcorning.com [kathy.plotzke@dowcorning.com]

Sent: 4/11/2018 1:21:46 PM

To: Morris, Jeff [Morris.Jeff@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

CC: Hanley, Mary [Hanley.Mary@epa.gov]; Clark, Sharon [Clark.Sharon@epa.gov]; michelle.d.andriot@dowcorning.com;

EHHeath@dow.com

Subject: RE: Potential meeting with Dow

Hi Jeff, thanks for coming back so quickly! Yes we can make a meeting at 3:00pm on April 24th. Also with Dow Corning integrating into Dow Chemical I thought it would be a good opportunity to talk about the resulting organizational changes, in particular as it relates to D4 and responsibility for the ECA in our company and introduce you to the new faces involved. Coming with me will be Michelle Andriot, Regulatory Affairs Manager, Americas and Eunice Heath, our Global Director, Environment, Health, Safety & Sustainability for our Consumer Solutions Business where Silicones now resides. Eunice is now our signatory on the ECA and has overall responsibility for EHS&S for D4 and other silicones products. One additional person Dennis Deziel, Director, Environmental and Regulatory Affairs from our DC office may attend if he is available but we are still checking his availability. As soon as we confirm if Dennis can attend as well I will let you know.

We are looking forward to the meeting! Please let us know location/entrance.

See you soon,

Kathy

Kathleen P. Plotzke, Ph.D.

Chief Health & Environmental Scientist Consumer Solutions The Dow Chemical Company Phone: (989) 496-8046

Fax: (989) 496-5595 cell phone: (989) 859-6748

e-mail: kathy.plotzke@dowcorning.com





From: Morris, Jeff [mailto:Morris.Jeff@epa.gov]

Sent: Tuesday, April 10, 2018 7:58 AM

To: Beck, Nancy <Beck.Nancy@epa.gov>; PLOTZKE, KATHLEEN P. (KPPLOTZK) <kathy.plotzke@dowcorning.com>

Cc: Hanley, Mary < Hanley. Mary@epa.gov>; Clark, Sharon < Clark. Sharon@epa.gov>

Subject: RE: Potential meeting with Dow

Hi Kathy. This month looks challenging for both of us. I can meet at 3:00 on the 24th. If that won't work, given our respective schedules we will have to look to early May.

All the best,

Jeff

From: Beck, Nancy

Sent: Monday, April 09, 2018 2:59 PM **To:** kathy.plotzke@dowcorning.com

Cc: Morris, Jeff < Morris.Jeff@epa.gov>; Hanley, Mary < Hanley.Mary@epa.gov>

Subject: RE: Potential meeting with Dow

Hi Kathy,

It was good to see you as well. Jeff Morris and I were chatting this morning about this and as I starting point, he thought it would be more helpful if your group started the conversations with him and his team and then perhaps loop me in afterwards. That approach seems to make sense to me.

I hope this is workable. I've looped in Jeff so he can take a look at his schedule..

Regards, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: kathy.plotzke@dowcorning.com [mailto:kathy.plotzke@dowcorning.com]

Sent: Friday, April 6, 2018 1:11 PM

To: Beck, Nancy < Beck. Nancy@epa.gov > Subject: Potential meeting with Dow

Hi Nancy, it was nice to see you at SOT. I have discussed internally here at Dow and we would be interested in meeting with you (and others as appropriate) to discuss the potential next steps on D4. If you could look at some potential dates/times that would be very much appreciated. We could be in DC next week (week of April 9th) as well as the last week in April (week of the 23rd). I am traveling in Europe the week of April 16th so that week is out. Let me know if this would be possible and what dates/times might work for you.

Kind regards,

Kathy

Kathleen P. Plotzke, Ph.D.

Chief Health & Environmental Scientist Consumer Solutions The Dow Chemical Company Phone: (989) 496-8046

Fax: (989) 496-5595 cell phone: (989) 859-6748

e-mail: kathy.plotzke@dowcorning.com



From: Melissa Hockstad [MHockstad@CleaningInstitute.org]

Sent: 4/10/2018 6:07:05 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

CC: Bolen, Derrick [bolen.derrick@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]

Subject: RE: Response Requested - Meeting with ACI Board Members on Wed., June 20

Thanks Nancy.

I will reach out to Derrick to lock down an agenda and window that works for all. I hope you have a great week.

Kind regards, Melissa

From: Beck, Nancy <Beck.Nancy@epa.gov> Sent: Tuesday, April 10, 2018 12:46 PM

To: Melissa Hockstad < MHockstad@CleaningInstitute.org >

Cc: Bolen, Derrick <bolen.derrick@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov> Subject: RE: Response Requested - Meeting with ACI Board Members on Wed., June 20

Hi Melissa,

Thank you for checking in so far in advance and for the opportunity to meet with your Board of Directors. As you are likely aware, June 22 is a big day for our TSCA program and in all likelihood we will be working hard to get about 5 additional substantive items finalized out the door on that date. Having said that, if your group was willing to come, here hopefully we could find 30 minutes of calm within the storm to chat for a bit. I'm quite sure I won't be doing any travel that week.

I would suggest that you work with Derrick Bolen to lock down a window and an agenda that works for us all. Many thanks, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

Marie Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Melissa Hockstad [mailto:MHockstad@CleaningInstitute.org]

Sent: Monday, April 9, 2018 3:33 PM
To: Beck, Nancy < Beck. Nancy@epa.gov>

Subject: Response Requested - Meeting with ACI Board Members on Wed., June 20

Hi Nancy.

I hope you are doing well. I have an advanced planning question for you. On the afternoon of Wednesday, June 20 members of the American Cleaning Institute's (ACI's) Board of Directors will be in Washington. I wanted to know if you would have a 30-45 minute block that afternoon to meet with them either at the EPA HQ or at ACI's office. ACI's Board is made up of senior executives from both cleaning product formulators as well as from ingredient manufacturers.

The purpose of the meeting would be to introduce them to the Office of Chemical Safety and Pollution Prevention and to discuss items specific to TSCA implementation. We would fine tune the agenda as we got closer to June.

I know your schedule gets very busy so please let me know if you would have time to meet with members of the ACI Board of Directors. I would anticipate up to a dozen people at the meeting. I look forward to hearing from you. Thank you.

Kind regards, Melissa

Melissa Hockstad | President & CEO | American Cleaning Institute® 1331 L Street NW, Suite 650, Washington, DC 20005 | p: 202.662.2504 mhockstad@cleaninginstitute.org





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From: lschaaff@hess.com [lschaaff@hess.com]

Sent: 4/2/2018 3:01:56 PM

To: Jennifer Thompson [jennifer.thompson@shell.com]; elitr@dongenergy.com; Gunasekara, Mandy

[Gunasekara.Mandy@epa.gov]; Swink, Suzanne [Suzanne.Swink@bp.com]; Personal Email / Ex. 6 } Misty Mcgowen [Misty.McGowen@p66.com]; Elizabeth.boylan@solvay.com; Souza, Victoria [VSouza@hess.com]; Sarah Gainer [sarah.gainer@chk.com]; Burhop, Anna [anna.burhop@bracewell.com]; Holly Hopkins [hopkinsh@api.org];

Bolen, Brittany [bolen.brittany@epa.gov]; Elizabeth Craddock [Elizabeth.Craddock@iadc.org]; megan.miller@mail.house.gov; Mary Martin [mary.martin@mail.house.gov]; Kate MacGregor

[katharine_macgregor@ios.doi.gov]; Lisa Ceglia [Lisa.Ceglia@smiths.com]; Kime, Robin [Kime.Robin@epa.gov];

Elisabeth-Anne Treseder [ELITR@orsted.com]; Carrie Domnitch [domnitchc@api.org]; Amy Farrell

Personal Email / Ex. 6 ; leger [stephanie@legerstrategies.com]; Kristin.Whitman@shell.com; MSHUT@statoil.com;

Laura E Vaught [Laura.E.Vaught@dominionenergy.com]; kayla.dolan@mail.house.gov; Hilary Moffett [moffetth@api.org]; Beck, Nancy [Beck.Nancy@epa.gov]; Patricia.Tamez@shell.com; Bertrand, Charlotte

[Bertrand.Charlotte@epa.gov]; Smith, Jennifer [Smith.Jennifer@chevron.com]

Subject: FW: Women in Energy

Location: Proper 21 1319 F St NW, Washington, DC 20004

Start: 4/26/2018 9:00:00 PM

End: 4/27/2018 Show Time As: Tentative

Recurrence: (none)

Hi all. Trying this again....

Come to Happy Hour on Thursday, 4/26 at 5PM at Proper 21 (near Metro Center) to catch up with friends in the energy/environment field. All are welcome – feel free to forward this invitation.

Lesley Schaaff

lschaaff@hess.com

202-257-0316

From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 6/12/2019 8:53:55 PM

To: Henry, Tala [Henry.Tala@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]

CC: Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; LaFore, Mike (M)

[m.lafore@dow.com]; Schisler, Melissa (R) [MRSchisler@dow.com]; Morris, Jeff [Morris.Jeff@epa.gov]

Subject: Re: PMN Status Inquiry

Thank you!

Get Outlook for iOS

From: Henry, Tala Henry.Tala@epa.gov **Sent:** Wednesday, June 12, 2019 4:52:08 PM **To:** Dunn, Alexandra; Deziel, Dennis (DR)

Cc: Beck, Nancy; Bertrand, Charlotte; LaFore, Mike (M); Schisler, Melissa (R); Morris, Jeff

Subject: RE: PMN Status Inquiry

Hi Dennis,

The OPPT Team has completed review of the additional analogue data/analysis Dow submitted to the Agency in mid-February of this year.

The OPPT Program Manager has been in contact with Dow's Technical Contact today. EPA is now awaiting input from Dow to complete the determination for the case.

Please let me know if any additional issues arise.

Thank you,

Tala

Tala R. Henry, Ph.D.
Deputy Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959 E: henry.tala@epa.gov

From: Dunn, Alexandra

Sent: Wednesday, June 12, 2019 9:34 AM **To:** Deziel, Dennis (DR) < DRDeziel@dow.com>

Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; LaFore, Mike (M) <m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>; Morris, Jeff <Morris.Jeff@epa.gov>; Henry, Tala

<Henry.Tala@epa.gov>

Subject: Re: PMN Status Inquiry

We will follow up of course. Thank you for reaching out.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator

Office of Chemical Safety & Pollution Prevention

U.S. Environmental Protection Agency Washington, DC

Sent from my iPhone

On Jun 12, 2019, at 9:26 AM, Deziel, Dennis (DR) < DRDeziel@dow.com > wrote:

Alex,

Sorry to bother you again on this but the lack of progress or updates has become a serious business issue for Dow. Is it possible to get an update? Thank you, Dennis

From: Deziel, Dennis (DR)

Sent: Tuesday, April 30, 2019 8:57 AM

To: dunn.alexandra@epa.gov

Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand.charlotte@Epa.gov; LaFore, Mike (M)

<m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: FW: PMN Status Inquiry

Good morning, Alex.

Any help on this would be appreciated. Months with no sense of action or progress. Thank you, Dennis

Dennis Deziel

Director, Federal Government Affairs

Dow

500 North Capitol Street, NW Washington DC 20001 phone: 202.429.3420 | email: DRDeziel@dow.com

Mobile: 301.385.1284

<image002.jpg>

From: Deziel, Dennis (DR)

Sent: Monday, April 15, 2019 11:46 AM

To: 'Morris.jeff@Epa.gov' < Morris.jeff@Epa.gov>

Cc: 'Beck, Nancy' <Beck.Nancy@epa.gov'; 'Bertrand.charlotte@Epa.gov' <Bertrand.charlotte@Epa.gov';

LaFore, Mike (M) <m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: RE: PMN Status Inquiry

Resending. Thanks

From: Deziel, Dennis (DR)

Sent: Wednesday, April 10, 2019 9:48 AM

To: Morris.jeff@Epa.gov

Cc: Beck, Nancy < Bertrand.charlotte@Epa.gov; LaFore, Mike (M)

<m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: PMN Status Inquiry

Jeff,

We've had PMN (P-18-0170) under review since May 2018 and we are unclear on process and timeline. The new substance has won several awards, including a R&D 100 award, and just won a 2019 Edison Award (see press release below). This is an example of new technology which "...reduces water, dye, energy, and chemical use..." in the textile dyeing process.

Can you please provide a sense of status and possibly target end date? We are available to meet if you think that is warranted. Thank you, Dennis

MIDLAND, Mich. - April 08, 2019

Silver to ECOFAST™ Pure Sustainable Textile Treatment: ECOFAST™ Pure is a breakthrough technology that enables unique, brighter colors on cotton textiles while helping address sustainability challenges in the industry, including quality and consumption of water. This patented technology reduces water, dye, energy and chemical use in the dyeing process and meets the ZDHC Roadmap to Zero Programme standards. ECOFAST Pure is compatible with reactive, direct and acid dyes and can be applied to knit and woven fabric, denim and garments.

Dennis Deziel

Director, Federal Government Affairs

Dow

500 North Capitol Street, NW Washington DC 20001 phone: 202.429.3420 | email: <u>DRDeziel@dow.com</u>

Mobile: 301.385.1284

<image004.jpg>

From: Schaaff, Lesley [Ischaaff@hess.com]

Sent: 3/20/2018 5:18:52 PM

To: ceglial@api.org; Jennifer Thompson [jennifer.thompson@shell.com]; elitr@dongenergy.com; Gunasekara, Mandy

[Gunasekara.Mandy@epa.gov]; Swink, Suzanne [Suzanne.Swink@bp.com]; Personal Email / Ex. 6 | Misty Mcgowen [Misty.McGowen@p66.com]; Puneet Verma [PVerma@chevron.com]; Elizabeth.boylan@solvay.com; Amy Farrell [FarrellA@api.org]; Souza, Victoria [VSouza@hess.com]; Sarah Gainer [sarah.gainer@chk.com]; Burhop, Anna

[anna.burhop@bracewell.com]; Holly Hopkins (hopkinsh@api.org) [hopkinsh@api.org]; Bolen, Brittany

[bolen.brittany@epa.gov]; Elizabeth Craddock [Elizabeth.Craddock@iadc.org]; megan.miller@mail.house.gov; Mary

Martin (mary.martin@mail.house.gov) [mary.martin@mail.house.gov]; Kate MacGregor

(katharine_macgregor@ios.doi.gov) [katharine_macgregor@ios.doi.gov]; Lisa Ceglia (Lisa.Ceglia@smiths.com) [Lisa.Ceglia@smiths.com]; Kime, Robin [Kime.Robin@epa.gov]; Carrie Domnitch [domnitchc@api.org]; Amy Farrell [Personal Email / Ex. 6] leger [stephanie@legerstrategies.com]; Kristin.Whitman@shell.com; MSHUT@statoil.com;

Laura E Vaught [Laura.E.Vaught@dominionenergy.com]; kayla.dolan@mail.house.gov; Hilary Moffett [moffetth@api.org]; Beck, Nancy [Beck.Nancy@epa.gov]; Patricia.Tamez@shell.com; Bertrand, Charlotte

[Bertrand.Charlotte@epa.gov]

CC: Elisabeth-Anne Treseder [ELITR@orsted.com]; Smith, Jennifer [Smith.Jennifer@chevron.com]

Subject: Women's Energy Gathering

Hi all. Due to the expected weather challenges in DC tomorrow, we are going to reschedule this get together for a date in April. Stay tuned and hope to see you all soon.

Lesley Schaaff
Senior Manager, Regulatory Affairs
Government & External Affairs
HESS CORPORATION

Office: 202-263-1012 Cell: 202-257-0316 lschaaff@hess.com

From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 2/16/2018 3:41:43 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: FW: Non-Order SNUR

Flag: Follow up

I am getting pressure internally due to the EPA silence on this. Can you help?

From: Deziel, Dennis (DR)

Sent: Tuesday, February 13, 2018 10:31 AM **To:** Mottley, Tanya <mottley.tanya@epa.gov>

Subject: RE: Non-Order SNUR

Resending @

From: Deziel, Dennis (DR)

Sent: Thursday, February 08, 2018 7:55 AM **To:** Mottley, Tanya <mottley.tanya@epa.gov>

Subject: Re: Non-Order SNUR

Tanya,

Our PMN case was submitted in November 2016 and EPA completed its review in July 2017, however the PMN case remains open. With the uncertainty around the publication of the non-Order SNURs, is EPA willing to consider issuing a 5(e) Consent Order with testing pended and a "may present" determination? While we prefer the non-Order SNUR route, at this point, we need to consider what may present the most expeditious route to commercialization.

Thank you, Dennis

From: Mottley, Tanya < mottley.tanya@epa.gov >

Sent: Tuesday, February 6, 2018 3:41 PM

Subject: RE: Non-Order SNUR

To: Deziel, Dennis (DR) <drdeziel@dow.com>

Hi Dennis, and thanks for your message. I think publication this week or next week is unlikely. The document hasn't left EPA yet for publication by the Office of the Federal Register, and is still going through EPA management review. Given that this is the first of these documents we're trying to publish, the review period has become rather lengthy (and as such, less predictable). I'm not in the office until Thursday of this week (I'm on travel now), but when I'm back at work, I'll check on where it is in the review process.

At this point, I'm reluctant to tell you a target publication timeframe. Hopefully it would be before the end of this month, but I can't say for certain.

Tanya

Tanya Hodge Mottley
Acting Deputy Director of Programs

Office of Pollution Prevention and Toxics, OCSPP (202) 564-3152

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Tuesday, February 06, 2018 3:35 PM **To:** Mottley, Tanya < <u>Mottley, Tanya@epa.gov</u>>

Subject: Non-Order SNUR

Hi Tanya,

Still looking like this week for publishing? Thanks!

Get Outlook for iOS

BRADLEY Kevin [kbradley@bsef.org] From:

2/12/2018 2:31:35 PM Sent:

To: Michael Dourson Personal Email / Ex. 6 ; sminick@txbiz.org; sferenc@cpda.com; raj.sharma@gapac.com;

Personal Email / Ex. 6 j jarchbo@toronto.ca; Henry Roman [HRoman@indecon.com]; dmccarty@dnr.state.ga.us; chenai@ucmail.uc.edu; aoller@nipera.org; ansellj@personalcarecouncil.org; anikiforov@toxregserv.com;

abegaze@ajiusa.com; SBennett@cspa.org; abraham.tobia@fda.hhs.gov; Eileen.Abt@fda.hhs.gov;

abennett@aeiconsultants.com; Jennifer.Adams@kochps.com; Admon Smadar - ICL - Industrial Products

; { Personal Email / Ex. 6 ; Ahmet. Bulbulkaya@tn.gov; [smadar.admon@icl-group.com]; Personal Email / Ex. 6 Akerman, Gregory [Akerman.Gregory@epa.gov]; Personal Email / Ex. 6 ; ali.furmall@state.nm.us;

Personal Email / Ex. 6 ; Acooke@kellencompany.com; aowen@dragun.com; amy.wehnert@amec.com; MANDERSO@idem.IN.gov; Steve.Anderson@albemarle.com; agthiros@uss.com; aumyn@walshenv.com; angela.limuller@hc-sc.gc.ca; Anita.K.Meyer@usace.army.mil; abradley@integral-corp.com; Davis Ann - Dow [aedavis@dow.com]; de Peyster Ann - San Diego State University [adepeyst@mail.sdsu.edu]; Anne LeHuray

[alehuray@naphthalene.org]; dietz.annette@deq.state.or.us; And6@cdc.gov; flood@ific.org; Asheesh.Tiwary@chevron.com; aprescott@tectest.com; adstuerke@terracon.com; ashley.winkelman@cardno.com;

nlove@cgs.us.com; Asish Mohapatra [asish.mohapatra@hc-sc.gc.ca]; audrey.rush@epa.state.oh.us; a.boobis@imperial.ac.uk; joseph.brune.2.ctr@us.af.mil; Ryan_Baldwin@americanchemistry.com; bbeck@gradientcorp.com; MBasu@gmaonline.org; Audrey.Batoon@Chemtura.com; Beck, Nancy [Beck.Nancy@epa.gov]; Rick_Becker@americanchemistry.com; Clark, Becki [Clark.Becki@epa.gov]; bclement@burnsmcd.com; ben.stanphill@arcadis-us.com; Diane.Benford@foodstandards.gsi.gov.uk;

benjamin.davies@icmm.com; benny.dehghi@honeywell.com; Benson, Bob [Benson.Bob@epa.gov]; bertrand.langlet@hc-sc.gc.ca; bmeek@uottawa.ca; bhat@nsf.org; Sundar, Bhooma [sundar.bhooma@epa.gov]; bill.goulet@axiall.com; Gulledge Bill - American Chemistry Council (The) [bill_gulledge@americanchemistry.com];

birnbaumls@niehs.nih.gov; matthew.blais@swri.org; blayne@hartmaneg.com; Benson, Bob

[Benson.Bob@epa.gov]; Personal Email / Ex. 6 ; rthielke@trininc.com; kim_boekelheide@brown.edu; bonnie.brooks@state.mn.us; booker@niehs.nih.gov; bcs@barr.com; brad.weaver@celanese.com;

bgentry@iwmconsult.com; seidman.brenda@epa.gov; bchapman@gfnet.com; Brent_Kobielush@cargill.com; roger.brewer@doh.hawaii.gov; bcochran@aeiconsultants.com; HOWARD, WILLIAM B GS-13 USAF AFMC

AFCEC/CZTE [william.howard.40@us.af.mil]; obrien.bridget@epa.gov; mcatee@ppg.com;

aaron.brogdon@squirepb.com; Personal Email / Ex. 6 bryan.leece@stantec.com; burleighflayer@ppg.com; Shelley.Burman@state.mn.us; Burr Alexa - American Chemistry Council (The) [Alexa_Burr@americanchemistry.com]

Subject: RE: Rejoining TERA

Welcome back Mike,

Best wishes,

Kevin

Dr Kevin Bradley Secretary General



T: +32 2 792 75 49 | M: +353 86 100 85 50 | E: kbradley@bsef.org

BSEF, aisbl - The International Bromine Council Avenue E. Van Nieuwenhuyse 4, 1160 Brussels - Belgium

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EU Transparancy Register No: 4641 9392 1314-91

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Personal Email / Ex. 6 From: Michael Dourson Sent: Monday, 12 February 2018 15:09 To: sminick@txbiz.org; sferenc@cpda.com; raj.sharma@gapac.com; Personal Email / Ex. 6 jarchbo@toronto.ca: hroman@indecon.com; dmccarty@dnr.state.ga.us; chenai@ucmail.uc.edu; aoller@nipera.org; ansellj@personalcarecouncil.org; anikiforov@toxregserv.com; abegaze@ajiusa.com; SBennett@cspa.org; abraham.tobia@fda.hhs.gov; Eileen.Abt@fda.hhs.gov; abennett@aeiconsultants.com; Jennifer.Adams@kochps.com; Admon Smadar - ICL - Industrial Products <smadar.admon@icl-group.com>; Personal Email / Ex. 6 Personal Email / Ex. 6; ahmet.bulbulkaya@tn.gov; Akerman.Gregory@epa.gov; Personal Email / Ex. 6; ali.furmall@state.nm.us; Personal Email / Ex. 6 ; Acooke@kellencompany.com; aowen@dragun.com; amy.wehnert@amec.com; MANDERSO@idem.IN.gov; steve.anderson@albemarle.com; agthiros@uss.com; aumyn@walshenv.com; angela.li-muller@hc-sc.gc.ca; Anita.K.Meyer@usace.army.mil; abradley@integral-corp.com; Davis Ann - Dow <aedavis@dow.com>; de Peyster Ann - San Diego State University <adepeyst@mail.sdsu.edu>; Anne LeHuray <alehuray@naphthalene.org>; dietz.annette@deq.state.or.us; and6@cdc.gov; flood@ific.org; asheesh.tiwary@chevron.com; aprescott@tectest.com; adstuerke@terracon.com; ashley.winkelman@cardno.com; nlove@cgs.us.com; Asish Mohapatra <asish.mohapatra@hc-sc.gc.ca>; audrey.rush@epa.state.oh.us; a.boobis@imperial.ac.uk; joseph.brune.2.ctr@us.af.mil; Baldwin Ryan - American Chemistry Council (The) <ryan baldwin@americanchemistry.com>; bbeck@gradientcorp.com; MBasu@gmaonline.org; Audrey.Batoon@Chemtura.com; Beck, Nancy <Beck.Nancy@epa.gov>; Rick Becker@americanchemistry.com; clark.becki@epa.gov; bclement@burnsmcd.com; ben.stanphill@arcadis-us.com; Diane.Benford@foodstandards.gsi.gov.uk; benjamin.davies@icmm.com; benny.dehghi@honeywell.com; Benson.Bob@epa.gov; bertrand.langlet@hc-sc.gc.ca; bmeek@uottawa.ca; bhat@nsf.org; sundar.bhooma@epa.gov; bill.goulet@axiall.com; Gulledge Bill - American Chemistry Council (The) < bill gulledge@americanchemistry.com >; birnbaumls@niehs.nih.gov; matthew.blais@swri.org; blayne@hartmaneg.com; benson.bob@epa.gov; Personal Email / Ex. 6 ; rthielke@trininc.com; kim_boekelheide@brown.edu; bonnie.brooks@state.mn.us; booker@niehs.nih.gov; bcs@barr.com; brad.weaver@celanese.com; bgentry@iwmconsult.com; BRADLEY Kevin <kbradley@bsef.org>; seidman.brenda@epa.gov; bchapman@gfnet.com; Brent Kobielush@cargill.com; roger.brewer@doh.hawaii.gov; bcochran@aeiconsultants.com; HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE /william.howard.40@us.af.mil>; obrien.bridget@epa.gov; mcatee@ppg.com; aaron.brogdon@squirepb.com; Personal Email / Ex. 6 bryan.leece@stantec.com; Burleigh-Flayer Heather - PPG Industries Inc.
<burleighflayer@ppg.com>; Shelley.Burman@state.mn.us; Burr Alexa - American Chemistry Council (The) <Alexa_Burr@americanchemistry.com> Subject: Rejoining TERA

Dear Colleagues

I am pleased to announce my return to the nonprofit 501c3 organization, *Toxicology Excellence for Risk Assessment* (TERA), as its Director of Science. As many of you know, TERA joined the University of Cincinnati, College of Medicine (https://med.uc.edu/eh/centers/rsc) two years ago and became known as the Risk Science Center (RSC). However, TERA always maintained an external nonprofit organization under the leadership of Dr. Patricia McGinnis in order to complete several contracts, including one with the Consumer Products Safety Commission.

TERA's Board of Trustees has decided to continue TERA as a nonprofit organization and remain a separate entity from the RSC. TERA's mission will emphasize hazard identification, dose response assessment, independent peer review, and public education. Dr. McGinnis will continue to serve as TERA's President leading the business and contributing to projects as a board-certified toxicologist.

As many of you also know, TERA's extensive collaborative work was woefully mischaracterized during my US EPA confirmation hearings. Responses to this mischaracterization can be viewed

at http://tera.org/TERAcollaborativework%2012.8.17.pdf. You may also wish to view https://tera.org/TERAcollaborativework%2012.8.17.pdf. You may also wish to view https://www.cincinnati.com/story/news/politics/2018/01/25/university-cincinnati-professor-former-uc-professor-dourson-picks-up-pieces-after-failed-controversi/1047685001/ for some additional thoughts on this confirmation process.

TERA looks forward to the opportunity to work with you in the future. If you are attending the annual meeting of the Society of Toxicology next month, please stop by our booth #555.

Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA Director of Science Toxicology Excellence for Risk Assessment 1250 Ohio Pike, Suite #197 Amelia, Ohio 45102-1239

dourson@tera.org twitter: mdourson 513-542-7475 419-892-2502 (Mondays) http://www.tera.org

Ali Hamade Personal Email / Ex. 6 From: 2/12/2018 2:13:39 PM Sent: Personal Email / Ex. 6 To: Michael Dourson sminick@txbiz.org; sferenc@cpda.com; raj.sharma@gapac.com; Personal Email / Ex. 6 jarchbo@toronto.ca; Henry CC: Roman [HRoman@indecon.com]; dmccarty@dnr.state.ga.us; chenai@ucmail.uc.edu; aoller@nipera.org; anselli@personalcarecouncil.org; anikiforov@toxregserv.com; abegaze@ajiusa.com; SBennett@cspa.org; abraham.tobia@fda.hhs.gov; Eileen.Abt@fda.hhs.gov; abennett@aeiconsultants.com; Jennifer.Adams@kochps.com; smadar.admon@icl-group.com; Personal Email / Ex. 6 Personal Email / Ex. 6 ; Ahmet.Bulbulkaya@tn.gov; Akerman, Gregory [Akerman.Gregory@epa.gov]; Personal Email / Ex. 6 | ali.furmall@state.nm.us; Acooke@kellencompany.com; aowen@dragun.com; amy.wehnert@amec.com; MANDERSO@idem.IN.gov; Steve.Anderson@albemarle.com; agthiros@uss.com; aumyn@walshenv.com; angela.li-muller@hc-sc.gc.ca; Anita.K.Meyer@usace.army.mil; abradley@integral-corp.com; aedavis@dow.com; adepeyst@mail.sdsu.edu; Anne LeHuray [alehuray@naphthalene.org]; dietz.annette@deq.state.or.us; And6@cdc.gov; flood@ific.org; Asheesh.Tiwary@chevron.com; aprescott@tectest.com; adstuerke@terracon.com; ashley.winkelman@cardno.com; nlove@cgs.us.com; Asish Mohapatra [asish.mohapatra@hc-sc.gc.ca]; audrey.rush@epa.state.oh.us; a.boobis@imperial.ac.uk; joseph.brune.2.ctr@us.af.mil; Ryan_Baldwin@americanchemistry.com; bbeck@gradientcorp.com; MBasu@gmaonline.org; Audrey.Batoon@chemtura.com; Beck, Nancy [Beck.Nancy@epa.gov]; Rick_Becker@americanchemistry.com; Clark, Becki [Clark.Becki@epa.gov]; bclement@burnsmcd.com; ben.stanphill@arcadis-us.com; Diane.Benford@foodstandards.gsi.gov.uk; benjamin.davies@icmm.com; benny.dehghi@honeywell.com; Benson, Bob [Benson.Bob@epa.gov]; bertrand.langlet@hc-sc.gc.ca; bmeek@uottawa.ca; bhat@nsf.org; Sundar, Bhooma [sundar.bhooma@epa.gov]; bill.goulet@axiall.com; Bill_Gulledge@americanchemistry.com; birnbaumls@niehs.nih.gov; matthew.blais@swri.org; blayne@hartmaneg.com; Personal Email / Ex. 6; rthielke@trininc.com; kim_boekelheide@brown.edu; bonnie.brooks@state.mn.us; booker@niehs.nih.gov; bcs@barr.com; brad.weaver@celanese.com; bgentry@iwmconsult.com; kbradley@bsef.org; seidman.brenda@epa.gov; bchapman@gfnet.com; Brent_Kobielush@cargill.com; roger.brewer@doh.hawaii.gov; bcochran@aeiconsultants.com; HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE [william.howard.40@us.af.mil]; obrien.bridget@epa.gov; mcatee@ppg.com; aaron.brogdon@squirepb.com; Personal Email / Ex. 6 ; bryan.leece@stantec.com; burleighflayer@ppg.com; Shelley.Burman@state.mn.us; Alexa_Burr@americanchemistry.com Re: Rejoining TERA Subject:

Good luck!

On Feb 12, 2018 09:08, "Michael Dourson" Personal Email / Ex. 6 wrote: Dear Colleagues

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Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA Director of Science Toxicology Excellence for Risk Assessment 1250 Ohio Pike, Suite #197 Amelia, Ohio 45102-1239

dourson@tera.org twitter: mdourson 513-542-7475 419-892-2502 (Mondays) http://www.tera.org From: Gibson, Jacqueline MacDonald [jackie.macdonald@unc.edu]

Sent: 2/6/2018 2:42:37 AM

To: Druwe, Ingrid [Druwe.Ingrid@epa.gov]

CC: drsg-l@indiana.edu; Beck, Nancy [Beck.Nancy@epa.gov]; Davis, Allen [Davis.Allen@epa.gov]; Rick Reiss

[rreiss@exponent.com]; Musso, Michael P. [Michael.Musso@hdrinc.com]; Ed Pfau [epfau@hullinc.com]; Lowney,

Carrie A [carrie.a.lowney@zoetis.com]; Ian Collins [Ian.Collins@ghd.com]; Blessinger, Todd [blessinger.todd@epa.gov]; Wayne Landis [Wayne.Landis@wwu.edu]; Dalaijamts, Chimeddulam [CDalaijamts@cvm.tamu.edu]; Barbara D. Beck [BBECK@gradientcorp.com]; Lorenz Rhomberg [Irhomberg@gradientcorp.com]; Mary Jane Calvey [mjcalvey@rwmsinc.com]; Woodall, George

[Woodall.George@epa.gov]; Haas,Charles [haas@drexel.edu]; Setzer, Woodrow [Setzer.Woodrow@epa.gov]; Wout

Slob [wout.slob@rivm.nl]; Chiu, Weihsueh [WChiu@cvm.tamu.edu]; Flowers, Lynn [Flowers.Lynn@epa.gov];

Schlosser, Paul [Schlosser.Paul@epa.gov]; Jarabek, Annie [Jarabek.Annie@epa.gov]; Berner, Ted [Berner.Ted@epa.gov]; Bette Meek [bmeek@uottawa.ca]; Gibson, Jacqueline MacDonald

[jackie.macdonald@unc.edu]; Philip Goodrum [pgoodrum@integral-corp.com]; Robby and Brandolyn Thran

Personal Email / Ex. 6; Kenneth Bogen [kbogen@exponent.com]; xly@bnu.edu.cn; Arno Swart

[arno.swart@rivm.nl]; Yeager, Raymond (Phil) [Raymond.Yeager@fda.hhs.gov]; riesd@michigan.gov; Robinan Gentry [rgentry@ramboll.com]; Petersen, Dan [Petersen.Dan@epa.gov]; Zemin Wang [zemwang@indiana.edu];

Scarano, Louis [Scarano.Louis@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Evans, John S.

[jevans@hsph.harvard.edu]; Putzrath, Resha M CIV USN NAVMCPUBHLTHCEN PORS (US) [resha.m.putzrath.civ@mail.mil]; Wright, Michael [Wright.Michael@epa.gov]; Kopylev, Leonid

[Kopylev.Leonid@epa.gov]; Swartout, Jeffrey [swartout.jeff@epa.gov]; Young, Melanie [Young.Melanie@epa.gov];

Janet Kester [jkester@newfields.com]; Farrar, David [Farrar.David@epa.gov]; Simmons, Jane

[Simmons.Jane@epa.gov]; Gift, Jeff [Gift.Jeff@epa.gov]; Theodore, Shaji [Shaji.Theodore@fda.hhs.gov];

Rick_Becker@americanchemistry.com

Subject: Re: Reminder: DRSG Monthly Meeting Today

Hi All,

I have on my calendar that we have our monthly meeting tomorrow. Unfortunately, I've been called to an 11:45-12:45 by folks above my pay grade, and I can't miss this one. I'll try calling in after my meeting to check in.

Please accept my apologies.

Jackie

Dr. Jacqueline MacDonald Gibson RTI University Scholar, 2017-2018

Associate Professor, Department of Environmental Sciences and Engineering

Gillings School of Global Public Health

University of North Carolina, Chapel Hill

Michael Hooker Research Center 0032

Campus Box 7431

Chapel Hill, NC 27599-7431

jackie.macdonald@unc.edu

Phone: 919-966-7892 Fax: 919-966-7911

http://www.unc.edu/~macdonaj/

On Jan 9, 2018, at 12:09 PM, Druwe, Ingrid wrote:

Proposed ideas for symposia:

- Dose Response and Law
- Success of DR
- Systematic review and DR
- Machine Learning & SR-Translate science to decision (jackie volunteered for this one)
- New data for use in DR; how to communicate data → Segway to symposia
- Attention to how to properly design experiments to inform DR
- Scott Auerbach- BMD Express-NIH version
- How to facilitate open data dose response health benefits- Dan Kruskie of Iowa (CatReg?); Neal Fann OAQPS BenMap

Moving meeting to 2^{nd} Tuesday in January to accommodate travel & holiday schedules. Please make note of new Adobe connect & web conferencing information

Call-in number(s) and access code(s)

Teleconference:
Adobe Connect:

Conference Line/Code / Ex. 6

From: Glenn Ruskin [G_Ruskin@acs.org]

Sent: 2/1/2018 11:39:25 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

CC: Bolen, Derrick [bolen.derrick@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]

Subject: Re: Introduction & Meeting Request

Many thanks Nancy.

Glenn

Glenn S. Ruskin
Director | External Affairs & Communications
Office of the Secretary and General Counsel
American Chemical Society
1155 Sixteenth Street, NW
Washington, DC 20036
202-872-4475
www.acs.org

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On Feb 1, 2018, at 6:14 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Hi Glenn,

Thanks for your message. I'm looping in Derrick Bolen who can help with the calendar.

Hopefully we can find a 30 minute window that works well.

I will also ask our acting Principal Deputy Assistant Administrator, Charlotte Bertrand, to join us.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Glenn Ruskin [mailto:G_Ruskin@acs.org]
Sent: Thursday, February 1, 2018 5:51 PM
To: Beck, Nancy < Beck.Nancy@epa.gov >
Subject: Introduction & Meeting Request

Nancy:

Good evening, I just left you a voicemail message and now following up with an email.

I would like to setup a meeting with you for myself and ACS Executive Director and CEO Tom Connelly for general introduction purposes as well as discuss the U.S.EPA Green Chemistry Challenge Awards program. Here are some dates and times that would work from our end, and hope that one of them might mesh well with your calendar:

February 19 – after 12:00 PM February 23rd & 27th – before 12:00 PM February 28th – Open

Please feel free to email me back or to call me at 202-872-4475. I look forward to speaking and meeting with you.

Glenn

Glenn S. Ruskin

Director | External Affairs & Communications
Office of the Secretary and General Counsel
American Chemical Society
1155 16th St., NW | Washington | DC 20036 | USA
T +1 202-872-4475 | F +1 202-872-6206

www.acs.org

ACS Chemistry for Life American Chemical Society

From: Timothy A. Brown [tbrown@cspa.org]

Sent: 1/24/2018 2:49:59 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: ABA SEER Group Speaking Invitation

Attachments: Nancy Beck Invite.pdf

Dear Nancy,

By way of introduction, this is Tim Brown from CSPA and we met last year soon after your appointment with my colleague Steve Bennett. I am a member of the American Bar Association's Section of Environment, Energy and Resources (SEER) group and attached is a formal invitation to speak at one our upcoming Friday Forums in March 2018. As always, should you have any questions regarding this invitation of the group in general, please don't hesitate to contact me.

Thanks in advance, Tim

Timothy A. Brown, Esq.

Vice President, Regulatory Counsel & International Affairs Consumer Specialty Products Association

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January 24, 2018

Dr. Nancy Beck
Deputy Assistant Administrator
Office of Chemical Safety and
Pollution Prevention
U.S. Environmental Protection Agency

Re: Speaking Invitation for March 2018 ABA SEER Group Friday Forum

Dear Nancy:

On behalf of the American Bar Association's Section of Environment, Energy and Resources (SEER) group, I am extending this formal invitation for you to speak at one of the upcoming Friday Forums in March 2018.

As you may already know, the ABA SEER group strives to be one of the premier forums for environmental, energy, and resources for lawyers as well as a meeting place where they can find the most current and sophisticated analyses of the complicated environmental, energy and resource problems facing the United States and the world and where they can learn, teach and contribute to solving those problems while serving the public interest. As part of this endeavor, the group plans monthly Friday Forums in the DC area to discuss a variety of important issues ranging from environment, regulatory compliance, energy, and legal issues in an effort to expand and sharpen the relevant perspectives on issues that are important for our members.

Specifically, as part of this Friday Forum series, we would be honored if you could join us one Friday in March on either the 9th or 16th to discuss current issues such as an overview of EPA's goals and priorities for 2018, TSCA-specific issues including the upcoming fees rule, the CBI/unique identifiers rule or any other topic you may feel is relevant to bring to this group's attention as we head into 2018. In addition, should these particular dates in March not work, we can also plan a Friday in April if that would work better for your schedule.

I hope you will be able to join us for one of our meetings. As highlighted above, we are currently aiming for March 9th or March 16th, but are completely open to slots in April should those dates not work on your end. In addition, we usually set aside roughly 30 minutes or so for speakers to present and provide an additional 15-20 minutes for questions. The tentative location for this program will be at Wiley Rein, LLP located at 1776 K St., NW. As always, please let me know if

1667 K Street, NW, Suite 300, Washington, DC 20006 | www.cspa.org | p.202-872-8110 f. 202-223-2636

you have any questions. I can be reached directly at 202-833-7303 or at tbrown@cspa.org. I hope that your schedule will permit you to speak at one of our upcoming forums and please do not hesitate to contact me should you need any additional information.

Very truly yours,

Timothy A. Brown

Vice President, Regulatory Counsel & International Affairs

Consumer Specialty Products Association

From: Owen Caine [ocaine@cspa.org]

Sent: 1/23/2018 5:14:33 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Time to chat

Flag: Flag for follow up

Hey Nancy,

I hope all is going well. I was wondering if you had a spare couple of minutes to chat on the phone on a couple issues. Let me know. Many thanks!

Owen Caine

Executive Vice President
Government Relations & Public Policy

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ocaine@cspa.org/ www.cspa.org

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From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 1/17/2018 9:52:24 PM

To: Bolen, Derrick [bolen.derrick@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Arrived

I believe I am the correct lobby as it is the epa building I have been in before, no hurry I know I am early. Came in off constitution avenue

Sent from my iPhone

From: Michael Dourson Personal Email / Ex. 6

Sent: 1/19/2018 7:41:10 PM

To: BOOBIS Alan [a.boobis@imperial.ac.uk]; BRUNE, JOSEPH M CTR USN AFMC NAMRU/Dayton

[joseph.brune.2.ctr@us.af.mil]; Ryan_Baldwin@americanchemistry.com; barbara.morin@dem.ri.gov; Barbara Beck [bbeck@gradientcorp.com]; MBasu@gmaonline.org; Batoon, Audrey [Audrey.Batoon@Chemtura.com]; Beck, Nancy [Beck.Nancy@epa.gov]; Ben Clement [bclement@burnsmcd.com]; Ben Stanphill [ben.stanphill@arcadis-us.com]; Benford, Diane [Diane.Benford@foodstandards.gsi.gov.uk]; Benjamin Davies [benjamin.davies@icmm.com]; Benny

Dehghi [benny.dehghi@honeywell.com]; Benson, Bob [Benson.Bob@epa.gov]; Bertrand Langlet [bertrand.langlet@hc-sc.gc.ca]; Bette Meek [bmeek@uottawa.ca]; bhat@nsf.org; Sundar, Bhooma

[sundar.bhooma@epa.gov]; Bill Goulet [bill.goulet@axiall.com]; Bing Wang [bingwang23@gwu.edu]; Birnbaum, Linda (NIH/NIEHS) [E] [birnbaumls@niehs.nih.gov]; Blais, Matthew [matthew.blais@swri.org]; Blayne Hartman [blayne@hartmaneg.com]; Benson, Bob [Benson.Bob@epa.gov]; Bob Thielke [rthielke@trininc.com]; Bobst, Sol

[SBobst@nexeosolutions.com]; Boekelheide, Kim [kim_boekelheide@brown.edu]; Bonnie Brooks

[bonnie.brooks@state.mn.us]; Boobis, Alan R [a.boobis@imperial.ac.uk]; Booker, Susan M (NIH/NIEHS) [E] [booker@niehs.nih.gov]; Brad Schwie [bcs@barr.com]; Brad Weaver [brad.weaver@celanese.com]; Bradley Gentry [bgentry@iwmconsult.com]; Bradley, Kevin [kbradley@bsef.org]; Brayden Ford [bford@bizinfogroup.ca]; Brenda

Seidman [seidman.brenda@epa.gov]; Brent Chapman [bchapman@gfnet.com]; BHicks1@idem.IN.gov; roger.brewer@doh.hawaii.gov; Brian Cochran [bcochran@aeiconsultants.com]; Brian Howard

(william.howard.40@us.af.mil) [william.howard.40@us.af.mil]; Brian Roden [brian.roden@amec.om]; Bridget O'Brien [obrien.bridget@epa.gov]; mcatee@ppg.com; Brogdon, Aaron T [aaron.brogdon@squirepb.com]; Bruce Allen Personal Email / Ex. 6 ; Bruce Bernel [Bruce.Bernel@firstmerit.com]; Bryan Elledge [bryan.elledge@kochind.com]; Bryan Leece [bryan.leece@stantec.com]; burleighflayer@ppg.com;

Burman, Shelley (MPCA) [Shelley.Burman@state.mn.us]; Burr, Alexa [Alexa_Burr@americanchemistry.com]

Subject: EPA Nomination

Dear Colleagues

As many of you know, President Trump nominated me last summer to be the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention in the US EPA. The nomination was quite exciting, but also humbling. I accepted and joined EPA as a senior advisor to the Administrator while waiting for US Senate confirmation. The ensuing months of web-based stories about my work at the nonprofit 501c3 Toxicology Excellence for Risk Assessment (TERA) and the University of Cincinnati were surprising. Seldom mentioned was TERA's balance of work between industry and government (1/3 industry, 2/3 government, see www.tera.org/funding), or multiple sector collaborations such as Beyond Science and

Decisions (http://med.uc.edu/eh/centers/rsc/risk-resources/dose-response-framework), or TERA's extensive peer review program (http://tera.org/Peer/MeetingReports/index.html), or TERA's publicly available databases, such as the International Toxicity Estimates for Risk (https://toxnet.nlm.nih.gov/newtoxnet/iter.htm). Moreover, selected projects were extensively mischaracterized, responses to which can now be viewed at https://www.tera.org/TERAcollaborativework%2012.8.17.pdf.

In order to avoid unnecessarily politicizing the important environmental protection goals of Administrator Pruitt, I asked President Trump last month to withdraw my name for consideration of this EPA position. The office is currently being lead under the capable hands of Charlotte Bertrand, Nancy Beck and Louise Wise.

I sincerely and deeply appreciate all the support from many of you during this confirmation process. I also look forward to continue working with you to protect both human health and the ecosystem from toxic levels of chemical exposures.

Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA

Personal Address / Ex. 6

---Those who have the privilege to know, have the duty to act. Albert Einstein

From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 1/12/2018 6:26:21 PM

To: Bolen, Derrick [bolen.derrick@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Re: Lunch

Perfect. Thank you!

Get Outlook for iOS

From: Bolen, Derrick <bolen.derrick@epa.gov>

Sent: Friday, January 12, 2018 1:24 PM

Subject: RE: Lunch

To: Deziel, Dennis (DR) <drdeziel@dow.com>, Beck, Nancy <beck.nancy@epa.gov>

Dennis-

How does 12pm work next Friday?

Thank you, Derrick Bolen

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Thursday, January 11, 2018 5:46 PM

To: Beck, Nancy < Beck. Nancy@epa.gov >; Bolen, Derrick < bolen.derrick@epa.gov >

Subject: Re: Lunch

Ha! Friday is usually good! Like next Friday.

GetOutlook for iOS

From: Beck, Nancy < <u>Beck.Nancy@epa.gov</u>>
Sent: Thursday, January 11, 2018 5:41:19 PM
To: Deziel, Dennis (DR); Bolen, Derrick

Subject: RE: Lunch

I have a meeting til noon.

Nice that you are still in the old EPA habit of 4 day work weeks...

Derrick can you help us find another window. Fridays are really best for me (sorry Dennis)...

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Thursday, January 11, 2018 5:31 PM

To: Beck, Nancy < Beck. Nancy@epa.gov>; Bolen, Derrick < bolen.derrick@epa.gov>

Subject: Re: Lunch

I have a 1pm train. Can we eat early?

GetOutlook for iOS

From: Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>
Sent: Thursday, January 11, 2018 5:22:26 PM

To: Deziel, Dennis (DR); Bolen, Derrick **Subject:** RE: Lunch

Does tomorrow work?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Tuesday, January 9, 2018 2:05 PM

To: Bolen, Derrick < bolen.derrick@epa.gov >; Beck, Nancy < Beck.Nancy@epa.gov >

Subject: Lunch

Nancy, Derrick -

Happy New Year! I'd like to schedule a quick lunch soon so we can catch up and maybe talk about a few issues, hear about your travels.

Please let me know. Thank you, Dennis

Dennis Deziel

Director, Federal Government Affairs
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From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 1/9/2018 4:10:01 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]
CC: Bolen, Derrick [bolen.derrick@epa.gov]

Subject: Re: Meeting?

Great, I should have most of the 17th afternoon available, early 18th, other? Hope we can find common time

Sent from my iPhone

On Jan 8, 2018, at 10:00 PM, Beck, Nancy < Beck. Nancy@epa.gov > wrote:

Hi Daland,

Derrick Bolen on our team can work with you to see if we can find 30minutes on the calendar. If they are available, I'd like to ask Rick Keigwin and Charlotte Bertrand to join us.

Thanks, Nancy

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP

P: 202-564-1273
M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Juberg, Daland (DR) [mailto:DRJuberg@dow.com]

Sent: Monday, January 8, 2018 10:44 AM **To:** Beck, Nancy <Beck, Nancy @epa.gov>

Subject: Meeting?

Hi Nancy – I'll be in Washington on other business on Jan. 18th, but will be coming in the 17th – in my new role as leader of human health science policy, I want to identify the top 3-5 core focal areas of issue prioritization for human health and will develop this thinking from discussions both internally and externally – I co-chair the CLA human health steering group and also sit on CLI's human health task force – I would value meeting with you to get your thoughts/thinking on core areas where there might be joint interest in EPA/multiple stakeholder engagement.

Do you have any availability on the 17th before I book air reservations as I would arrive earlier than normal if I could even get 30 minutes of your time?

Kind Regards,

Daland R. Juberg, Ph.D., Fellow, ATS Human Health Science Policy Regulatory Sciences

Dow AgroSciences LLC 9330 Zionsville Road, Indianapolis, IN 46268 Office: 317.337.3787 <u>DRJuberg@dow.com</u> www.dowagro.com

From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 1/11/2018 10:46:06 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]; Bolen, Derrick [bolen.derrick@epa.gov]

Subject: Re: Lunch

Ha! Friday is usually good! Like next Friday.

Get Outlook for iOS

From: Beck, Nancy <Beck.Nancy@epa.gov> Sent: Thursday, January 11, 2018 5:41:19 PM To: Deziel, Dennis (DR); Bolen, Derrick

Subject: RE: Lunch

I have a meeting til noon.

Nice that you are still in the old EPA habit of 4 day work weeks...

Derrick can you help us find another window. Fridays are really best for me (sorry Dennis)...

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Thursday, January 11, 2018 5:31 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>; Bolen, Derrick <bolen.derrick@epa.gov>

Subject: Re: Lunch

I have a 1pm train. Can we eat early?

Get Outlook for iOS

From: Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>
Sent: Thursday, January 11, 2018 5:22:26 PM
Tan Basis L Danie (DB), Balan Basis II

To: Deziel, Dennis (DR); Bolen, Derrick

Subject: RE: Lunch

Does tomorrow work?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Tuesday, January 9, 2018 2:05 PM

To: Bolen, Derrick < bolen.derrick@epa.gov>; Beck, Nancy < Beck.Nancy@epa.gov>

Subject: Lunch

Nancy, Derrick -

Happy New Year! I'd like to schedule a quick lunch soon so we can catch up and maybe talk about a few issues, hear about your travels.

Please let me know. Thank you, Dennis

Dennis Deziel

Director, Federal Government Affairs 500 North Capitol St NW, Suite 200, Washington, D.C. 20001 +1-202-429-3420 | +1-301-385-1284 (mobile - NEW!) | Drdeziel@dow.com

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WORLDWIDE PARTNER

From: Owen Caine [ocaine@cspa.org]

Sent: 1/2/2018 6:14:26 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Administrator Meeting

Hey Nancy,

I hope you had a great holiday and New Year. I wanted to let you know that we (CSPA) are putting in a request to meet with the Administrator. I thought it might be helpful four you and I to briefly talk about it before it happens. Let me know if you have any free time to chat on the phone briefly.

Many thanks!

Owen Caine

Executive Vice President
Government Relations & Public Policy



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From: Druwe, Ingrid [Druwe.Ingrid@epa.gov]

Sent: 1/9/2018 5:09:05 PM **To**: drsg-l@indiana.edu

CC: Beck, Nancy [Beck.Nancy@epa.gov]; Davis, Allen [Davis.Allen@epa.gov]; Rick Reiss [rreiss@exponent.com]; Musso,

Michael P. [Michael.Musso@hdrinc.com]; Ed Pfau [epfau@hullinc.com]; Lowney, Carrie A

[carrie.a.lowney@zoetis.com]; Ian Collins [Ian.Collins@ghd.com]; Blessinger, Todd [blessinger.todd@epa.gov]; Wayne Landis [Wayne.Landis@wwu.edu]; Dalaijamts, Chimeddulam [CDalaijamts@cvm.tamu.edu]; Barbara D. Beck

[BBECK@gradientcorp.com]; Lorenz Rhomberg [Irhomberg@gradientcorp.com]; Mary Jane Calvey

[mjcalvey@rwmsinc.com]; Woodall, George [Woodall.George@epa.gov]; Haas, Charles [haas@drexel.edu]; Setzer, Woodrow [Setzer.Woodrow@epa.gov]; Wout Slob [wout.slob@rivm.nl]; Chiu, Weihsueh [WChiu@cvm.tamu.edu];

Flowers, Lynn [Flowers.Lynn@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Jarabek, Annie

[Jarabek.Annie@epa.gov]; Berner, Ted [Berner.Ted@epa.gov]; Bette Meek [bmeek@uottawa.ca]; Gibson, Jacqueline MacDonald [jackie.macdonald@unc.edu]; Philip Goodrum [pgoodrum@integral-corp.com]; Robby and Brandolyn

Thran Personal Email / Ex. 6; Kenneth Bogen [kbogen@exponent.com]; xly@bnu.edu.cn; Arno Swart [arno.swart@rivm.nl]; Yeager, Raymond (Phil) [Raymond.Yeager@fda.hhs.gov]; riesd@michigan.gov; Robinan Gentry [rgentry@ramboll.com]; Petersen, Dan [Petersen.Dan@epa.gov]; Zemin Wang [zemwang@indiana.edu];

Scarano, Louis~[Scarano.Louis@epa.gov];~Bussard, David~[Bussard.David@epa.gov];~Evans, John~S.

[jevans@hsph.harvard.edu]; Putzrath, Resha M CIV USN NAVMCPUBHLTHCEN PORS (US) [resha.m.putzrath.civ@mail.mil]; Wright, Michael [Wright.Michael@epa.gov]; Kopylev, Leonid

[Kopylev.Leonid@epa.gov]; Swartout, Jeffrey [swartout.jeff@epa.gov]; Young, Melanie [Young.Melanie@epa.gov];

Janet Kester [jkester@newfields.com]; Farrar, David [Farrar.David@epa.gov]; Simmons, Jane

[Simmons.Jane@epa.gov]; Gift, Jeff [Gift.Jeff@epa.gov]; Theodore, Shaji [Shaji.Theodore@fda.hhs.gov];

Rick_Becker@americanchemistry.com

Subject: Reminder: DRSG Monthly Meeting Today

Location: Teleconference:

Conference Line/Code / Ex. 6

Start: 1/9/2018 5:00:00 PM **End**: 1/9/2018 6:00:00 PM

Show Time As: Tentative

Proposed ideas for symposia:

- Dose Response and Law
- Success of DR
- Systematic review and DR
- Machine Learning & SR-Translate science to decision (jackie volunteered for this one)
- New data for use in DR; how to communicate data → Segway to symposia
- Attention to how to properly design experiments to inform DR
- Scott Auerbach- BMD Express-NIH version
- How to facilitate open data dose response health benefits- Dan Kruskie of Iowa (CatReg?); Neal Fann OAQPS
 BenMap

Moving meeting to 2nd Tuesday in January to accommodate travel & holiday schedules. Please make note of new Adobe connect & web conferencing information

Call-in number(s) and access code(s)

Teleconference: Conference Line/Code / Ex. 6

Adobe Connect: Conference Line/Code / Ex. 6

From: Dunn, Alexandra [dunn.alexandra@epa.gov]

Sent: 6/12/2019 1:34:05 PM

To: Deziel, Dennis (DR) [DRDeziel@dow.com]

CC: Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; LaFore, Mike (M)

[m.lafore@dow.com]; Schisler, Melissa (R) [MRSchisler@dow.com]; Morris, Jeff [Morris.Jeff@epa.gov]; Henry, Tala

[Henry.Tala@epa.gov]

Subject: Re: PMN Status Inquiry

We will follow up of course. Thank you for reaching out.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, DC

Sent from my iPhone

On Jun 12, 2019, at 9:26 AM, Deziel, Dennis (DR) < DRDeziel@dow.com> wrote:

Alex,

Sorry to bother you again on this but the lack of progress or updates has become a serious business issue for Dow. Is it possible to get an update? Thank you, Dennis

From: Deziel, Dennis (DR)

Sent: Tuesday, April 30, 2019 8:57 AM

To: dunn.alexandra@epa.gov

Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand.charlotte@Epa.gov; LaFore, Mike (M)

<m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: FW: PMN Status Inquiry

Good morning, Alex.

Any help on this would be appreciated. Months with no sense of action or progress. Thank you, Dennis

Dennis Deziel

Director, Federal Government Affairs

Dow

500 North Capitol Street, NW Washington DC 20001 phone: 202.429.3420 | email: DRDeziel@dow.com

Mobile: 301.385.1284

<image002.jpg>

From: Deziel, Dennis (DR)

Sent: Monday, April 15, 2019 11:46 AM

To: 'Morris.jeff@Epa.gov' < Morris.jeff@Epa.gov>

Cc: 'Beck, Nancy' < Beck.Nancy@epa.gov>; 'Bertrand.charlotte@Epa.gov' < Bertrand.charlotte@Epa.gov>;

LaFore, Mike (M) <m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: RE: PMN Status Inquiry

Resending. Thanks

From: Deziel, Dennis (DR)

Sent: Wednesday, April 10, 2019 9:48 AM

To: Morris.jeff@Epa.gov

Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand.charlotte@Epa.gov; LaFore, Mike (M)

<m.lafore@dow.com>; Schisler, Melissa (R) <MRSchisler@dow.com>

Subject: PMN Status Inquiry

Jeff,

We've had PMN (P-18-0170) under review since May 2018 and we are unclear on process and timeline. The new substance has won several awards, including a R&D 100 award, and just won a 2019 Edison Award (see press release below). This is an example of new technology which "...reduces water, dye, energy, and chemical use..." in the textile dyeing process.

Can you please provide a sense of status and possibly target end date? We are available to meet if you think that is warranted. Thank you, Dennis

MIDLAND, Mich. - April 08, 2019

Silver to ECOFAST™ Pure Sustainable Textile Treatment: ECOFAST™ Pure is a breakthrough technology that enables unique, brighter colors on cotton textiles while helping address sustainability challenges in the industry, including quality and consumption of water. This patented technology reduces water, dye, energy and chemical use in the dyeing process and meets the ZDHC Roadmap to Zero Programme standards. ECOFAST Pure is compatible with reactive, direct and acid dyes and can be applied to knit and woven fabric, denim and garments.

Dennis Deziel

Director, Federal Government Affairs

Dow

500 North Capitol Street, NW Washington DC 20001 phone: 202.429.3420 | email: <u>DRDeziel@dow.com</u>

Mobile: 301.385.1284

<image004.jpg>

From: Papineni, Sabitha (S) [SPapineni@dow.com]

Sent: 12/4/2017 11:07:09 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]

CC: Bolen, Derrick [bolen.derrick@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Juberg, Daland (DR)

[DRJuberg@dow.com]

Subject: RE: PMN meeting

Attachments: DAS_PMN_Testing_Justification_Final.docx

Importance: High

Thank you very much Nancy.

Dear Greg,

Appreciate your time and consideration on this issue.

Would there be an opportunity to discuss this further and to reevaluate the testing requirements with OPPT? As Daland mentioned, the testing requirements of the PMNs were previously agreed on by DOW. However, we do not agree with the reasons driving the

requirement of an OECD 422 (the reproductive and developmental screening study) via inhalation). OPPT stated that they noted changes in pup body weights at the highest dose of 300 mg/kg/day with the analog (parent Rinskor active) in the two generation reproduction and they consider the changes to be adverse and thus PMNs could have the potential to induce the same. However, we disagree with OPPT's assessment of pup body weight changes and furthermore it also contrasted with HED's assessment of the data for Rinskor active. In Sep 2017 when granting an unconditional registration under FIFRA for Rinskor HED concluded that there are no treatment related effects to the parent or offspring at any dose levels tested. In addition, based on lack of toxicity for Rinskor, no point of departures were selected and no quantitative risk assessments were conducted.

Additional justification has been described in detail in the attached document (including exposure potential) for your review. Please note that OECD 422 will use significant number of rats, a total of ~800 rats including offspring.

Regarding the other endpoint of concern for OPPT, the skin sensitization- Rinskor is a weak dermal sensitizer and the registrant would be willing to assign sensitization classification for PMNs since appropriate risk mitigation measures such as standard OSHA required PPE are already in place for manufacturing workers. Thus, we requests a waiver for conducting an LLNA with the PMNs.

Based on this rationale and the discrepancy noted in the review of two-gen data between OPPT and HED based on which an OECD 422 was required, we would request OPPT for an opportunity to discuss this further and to reevaluate the testing requirements.

Thanking you,

Sabitha Papineni, DVM, Ph.D Senior Toxicologist Human Health Assessment Regulatory Sciences and Government Affairs Dow AgroSciences 9330 Zionsville Rd Indianapolis, IN-46268 Ph.317-337-6057 Fax.317-337-4880 E-mail:spapineni@dow.com From: Beck, Nancy [mailto:Beck.Nancy@epa.gov] Sent: Monday, December 04, 2017 12:30 PM

To: Juberg, Daland (DR) < DRJuberg@dow.com>

Cc: Bolen, Derrick <bolen.derrick@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Papineni, Sabitha (S)

<SPapineni@dow.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: PMN meeting

Thanks Daland.

Sabitha-

Since the time when you agreed to the order, have you had any discussions with Greg Schweer regarding the testing concerns?

If not, I suggest you have your first meeting with Greg. I have cc'd him above.

Regards, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Juberg, Daland (DR) [mailto:DRJuberg@dow.com]

Sent: Monday, December 4, 2017 7:25 AM **To:** Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>

Cc: Bolen, Derrick <bolen.derrick@epa.gov>; Hanley, Mary < Hanley.Mary@epa.gov>; Papineni, Sabitha (S)

<<u>SPapineni@dow.com</u>> **Subject:** RE: PMN meeting

Hi Nancy – yes, we are seeking a discussion on testing that was previously requested/agreed to – I am now going to simply bring in Sabitha Papineni to this discussion and ask her to liase with you and EPA directly on next steps. Thanks for your collective efforts.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, December 01, 2017 7:41 PM
To: Juberg, Daland (DR) < DRJuberg@dow.com>

Cc: Bolen, Derrick <bolen.derrick@epa.gov>; Hanley, Mary < Hanley.Mary@epa.gov>

Subject: RE: PMN meeting

Daland,

Apologies for the delay in getting back to you.

Staff are telling me that these PMNs are ones which EPA has approved and Dow has already commenced production. Is that correct?

Are you seeking a discussion on testing that was previously agreed to?

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6 beck.nancy@epa.gov

From: Juberg, Daland (DR) [mailto:DRJuberg@dow.com]

Sent: Thursday, November 16, 2017 8:51 AM **To:** Beck, Nancy < Beck. Nancy@epa.gov > **Cc:** Bolen, Derrick < bolen.derrick@epa.gov >

Subject: RE: PMN meeting

Nancy, Derrick – this is the high-level situation for your review and suggested next steps. I left the two PMN identifiers on Nancy's VM. Below summary is from the lead toxicologist on the team and based on your recommendation for next steps (30 min initial call, F2F meeting, etc.), I will then bring her/the team into this and let them lead from here with EPA. Many thanks.

OPPT has requested the following testing for Rinskor PMNs:

- 1) Genotox (Ames and micronucleus)
- 2) Dermal Sensitization
- 3) OECD 422 *via* inhalation with TK and or micronucleus (this is repeat dose toxicity combined with reproductive and developmental screening which requires 800 rats) (only for one of the intermediate- depending on the results, it will be triggered for other intermediate).

DAS rationale for not requiring the testing for PMNs:

A) Lack of Hazard potential for PMNs:

- 1) Rinskor (a new rice herbicide and the parent active) is considered as an appropriate surrogate or analog for these PMNs for read-across.
 - Rinskor (Florpyrauxifen benzyl) was granted unconditional registration under FIFRA as rice herbicide in September, 2017.
 - It was also granted a reduced risk designation based on it low human health risk profile.
 - Based on lack of toxicity for Rinskor, no point of departures were selected and no quantitative risk assessments were conducted.
- 2) The basis to ask for OECD 422 for was OPPT's evaluation of Rinskor two-generation reproduction study results indicating that the changes in pup body weights at the highest dose of 300 mg/kg/day. However, this assessment is in contrast to what HED has concluded suggesting that there are no treatment related effects to the parent or offspring at any dose levels tested with Rinskor.
- 3) Rinskor is a weak dermal sensitizer, DAS is willing to take sensitization classification for PMNs as appropriate risk mitigation measures such as standard OSHA required PPE are already in place for manufacturing workers.

B) Lack of Exposure Potential for PMNs:

- 1) Both PMNs have low vapor pressure reducing exposure potential via inhalation
- 2) Gastro plus Simulation and EPA's MPPD models consistently predicted a lower inhalation absorption for both PMNs.
- 3) Both PMNs are predicted to exhibit sublinear kinetics similar to Rinskor.
- 4) Most importantly, it is a closed manufacturing system reducing exposure to workers and
 - a. furthermore, workers wear PPE that minimizes both dermal and inhalation exposures
 - i. Supplied air breathing hood,
 - ii. Tyvek or PVC Suit,
 - iii. nitrile under neoprene gloves taped to suit

PBI / Ex. 4

PBI / Ex. 4

As per Lautenberg New Chemical Safety act requirement under Section 4 testing of chemicals by manufacturers, importers, and processors is only required "where risks or exposures of concern are found".

Based on the above rationale for Rinskor PMN substances, since there is no hazard or exposure potential, there is no Risk, DAS believes Rinskor PMN substances do not trigger the criteria for any additional testing.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Wednesday, November 15, 2017 9:00 AM
To: Juberg, Daland (DR) < DRJuberg@dow.com>
Cc: Bolen, Derrick < bolen.derrick@epa.gov>

Subject: PMN meeting

Daland,

Got your message and I presume you are referring to a new chemical issue. Happy to have a 30 minute meeting (phone or in person). Derek can help get it on my calendar and if you tell me or him the PMN number we can ensure correct experts attend as well. You may not want to email the PMN number as it may likely be CBI.

If you were referring to something else, just let me know the topic.

Regards, Nancy

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention

P: 202-564-1273

M: Personal Phone / Ex. 6 beck.nancy@epa.gov

Rinskor (parent) has been considered as an appropriate surrogate or analog for read-across by OPPT based on its structural similarity to the PMN substances being evaluated.

Requirement of an OECD 422 (the reproductive and developmental screening study) is not justified:

Although the Registrant agreed on the testing originally and signed the consent order, they do not agree with OPPT's rationale for requiring an OECD 422 (the reproductive and developmental screening study requiring 800 rats including pups). OPPT stated that they noted changes in pup body weights at the highest dose of 300 mg/kg/day with the analog in the two generation reproduction and they consider the changes to be adverse and thus PMNs would have the potential to induce the same.

However, the Registrant disagrees with OPPT's assessment of pup body weight changes. Furthermore, OPPT's assessment is also in contrast to HED's assessment of the data. In Sep 2017 when granting an unconditional registration under FIFRA for Rinskor HED concluded that there were no treatment related effects to the parent or offspring at any dose levels tested with Rinskor. In addition, based on lack of toxicity for Rinskor, no point of departures were selected and no quantitative risk assessments were deemed necessary.

Pup body weight data for the P1 and P2 generations from the two generation reproduction study are summarized below [refer to Tables 60 and 61; individual data reported in Appendix Tables 52 and 53 of the study report (ID: 130853)].

There were no treatment-related effects observed on pup body weights at any time during the study in either the F1 or F2 generations (Text Tables 1). Although the pup bodyweights at 300 mg/kg/day were slightly lower than controls in both genders in both generations, the pup body weights were not statistically identified and were near or within historical control range for two-generation studies conducted within the laboratory (Text Table 1 and 2). Moreover, there were no changes in any other offspring parameters-litter size, pup survival, sex ratio or puberty onset in either the P1 or P2 generations at any dose level tested with Rinskor.

Therefore, the Registrant does not believe that the basis for OPPT to require OECD 422 testing using a total of 800 rats per study is scientifically justified.

Negligible Exposure Potential for PMNs:

Registrant would also like to indicate that exposure potential via inhalation for these PMNs is also negligible based on low vapor pressure and simulation modeling data showing lower absorption via inhalation. Most importantly, PMNs are manufactured in almost a closed system with workers requiring to wear PPE that includes supplied air breathing hood with Tyvek or PVC suit with nitrile under neoprene gloves taped to suit reducing both dermal and inhalation exposures.

- Furthermore, pesticide intermediate is the only use for these PMNs and reasons why uses may not be expanded are provided below:
 - 1) Patent protected until 2032 and beyond
 - Generic production unlikely for 12-15 years due to barrier to entry with data compensability under FIFRA statues
 - 3) Complex synthetic route and no closely related analogs

Waiver for the Skin Sensitization study requirement:

Regarding the other endpoint of concern for OPPT, the skin sensitization-Rinskor is a weak dermal sensitizer and the registrant is willing to take sensitization classification for PMNs since appropriate risk mitigation measures such as standard OSHA required PPE are already in place for manufacturing workers. Thus requests a waiver for conducting an LLNA with the PMNs.

Text Table 1 Mean Pup Body Weights

	F1 Mean pup body weight				F2 Mean Pup Body				HCD	
Dose Level (mg/kg/day)	0	10	50	300	0	10	50	300	Range	
PND 1 (BC) Female	6.9	7.0	6.9	6.8	6.7	6.9	6.8	6.7	6.5-7.1	
PND 1 (BC) Male	7.4	7.3	7.2	7.2	7.2	7.3	7.2	7.1	6.8-7.5	
PND 4 (BC) Female	10.1	10.2	9.9	9.5	9.7	9.8	9.8	9.3	9.3-10.3	
PND 4 (BC) Male	10.6	10.5	10.3	10.0	10.4	10.3	10.4	9.9	9.7-10.7	
PND 4 (AC) Female	10.1	10.2	9.9	9.5	9.8	9.8	9.8	9.3	9.3-10.3	
PND 4 (AC) Male	10.6	10.5	10.3	10.0	10.4	10.3	10.4	9.9	9.7-10.7	
PND 7 (AC) Female	16.2	16.5	16.3	15.5	15.8	16.2	16.0	15.4	15.1-16.7	
PND 7 (AC) Male	17.0	17.0	16.9	16.1	16.7	16.9	16.9	16.3	15.7-17.5	
PND 14 (AC) Female	34.0	34.2	34.1	32.7	33.9	35.0	35.0	34.3	32.4-35.4	
PND 14 (AC) Male	35.0	34.7	35.0	33.7	35.5	35.8	36.5	35.7	33.6-36.6	
PND 21 (AC) Female	53.4	55.0	54.9	52.3	54.9	55.9	56.4	53.4	52.6-57.2	
PND 21 (AC) Male	55.2	55.9	56.7	53.7	58.0	57.3	59.2	56.1	54.7-59.5	

BC = Before culling AC= After culling

Text Table 2. Historical Control Data -Pup Body Weight

Study # Year Route	1-F1 2010 Dietary	1-F2 2010 Dietary	2-F1 2011 Dietary	2-F2 2011 Dietary	3-F1 2013 Dietary	3-F2 2013 Dietary	Average	Range	
Day 1 (BC) Female	6.9	6.7	7.1	6.5	7.0	6.7	6.8	6.5-7.1	
Day 1 (BC) Male	7.3	7.1	7.5	6.8	7.3	7.1	7.2	6.8-7.5	
Day 4 (BC) Female	10.0	9.6	10.3	9.3	10.2	9.7	9.9	9.3-10.3	
Day 4 (BC) Male	10.6	10.2	10.7	9.7	10.6	10.2	10.3	9.7-10.7	
Day 4 (AC) Female	10.1	9.7	10.3	9.3	10.3	9.7	9.9	9.3-10.3	
Day 4 (AC) Male	10.6	10.2	10.7	9.7	10.7	10.2	10.4	9.7-10.7	
Day 7 (AC) Female	16.7	16.1	16.3	15.1	16.6	16.6	16.2	15.1- 16.7	
Day 7 (AC) Male	17.4	16.8	16.8	15.7	17.3	17.5	16.9	15.7- 17.5	
Day 14 (AC) Female	34.9	34.7	33.5	32.4	34.6	35.4	34.3	32.4- 35.4	
Day 14 (AC) Male	36.1	35.6	34.3	33.6	35.5	36.6	35.3	33.6- 36.6	
Day 21 (AC) Female	57.2	55.7	54.9	52.6	55.8	56.7	55.5	52.6- 57.2	
Day 21 (AC) Male	59.5	57.8	55.9	54.7	57.5	58.9	57.4	54.7- 59.5	
DC = Defens culling									

BC = Before culling
AC= After culling
Minimum value for pup body weight data in **bold type**.

Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

November 30, 2017

Michael L. Goodis Director, Registration Division (7505P) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001

Dear Mr Goodis,

The Pyrethrum Joint Venture (PJV) would like to bring to your attention a very important issue that has occurred to our members and customers who market products containing the active ingredient Pyrethrins. Recently through the Re-Registration Process, member companies and customers have received letters informing them that efficacy data on file with the EPA that was used to support efficacy claims no longer meets EPA criteria and needs to be resubmitted or claims will be removed from the labels.

Products containing the active ingredient Pyrethrins have been marketed and used by consumers for many years and has showed to be effective against a broad spectrum of insects. These products are a very important tool in protecting people and their environment from the impact of insects. Pyrethrins offer very unique attributes that consumer's value in the products they choose for treating sensitive areas against the pressure of insects. Pyrethrins are one of a few botanical insecticides derived from a natural plant that is registered with the EPA's Registration Division, they have a safe history of use and have little environmental persistence. Pyrethrins have broad tolerances and uses including applications in food handling establishments, meat and milk tolerances, uses on companion animals and can be applied on a broad number of minor, but important crops like berries, fruits and a variety of vegetables. Pyrethrins are also a very important tool in protecting Public Health against vector borne diseases in mosquito control and also those insects found in homes.

The PJV feels that the process implemented by EPA to re-review efficacy data that was previously accepted by the agency and now claim as deficient is seriously flawed. EPA informed registrants that the efficacy data on file for several products does not meet EPA's current internal efficacy standards. To request new efficacy be generated on such a broad portfolio of products that contain many combinations of actives without formal guidelines is from our perspective, a premature and unnecessary regulatory action. The Reregistration process was implemented for EPA to review for missing scientific data and assess human health and ecological impacts. Biological efficacy and performance of these products does not impact human health or the environment. More importantly efficacy data, should not be identified as requiring resubmission unless EPA guidelines have been established. Without established guidelines first, "internal standards" for efficacy testing design can once again change and as registrations folders are later reopened, the "new" data could no longer be acceptable.

Finally, the PJV as suppliers and registrants of products containing Pyrethrins, are very confident our products work and provide consumers a valuable solution to their pest problems. Products containing Pyrethrins have been registered and used in the marketplace for many years and have proven to be effective against several public health pests. The performance of product containing Pyrethrins have been well established by the marketplace and documented in scientific journals and articles. EPA requesting new studies to replace already acceptable studies is an unnecessary burden of resources for both EPA and Industry.

Sincerely,

Sara M. Shikler

Sara Stickler

Vice President, Research & Education Research & Regulatory Management Council Consumer Specialty Products Association, Inc.

cc. Rick Keigwin, Director, Office of Pesticide Programs
Nancy Beck, Deputy Assistant Administrator, Office of Chemical Safety and Pollution
Prevention
Arnold Lane, Deputy Office Director for Management

Appendix 1

MEMBERS PYRETHRIN STEERING COMMITTEE/JOINT VENTURE November 2017

BASF, The Chemical Company Research Triangle Park, NC

Botanical Resources Australia Pty, Ltd. Tasmania, AUSTRALIA, 7005

Central Garden & Pet Walnut Creek, CA 94597

Horizon SOPYRWA Musanze, RWANDA

MGK Co. Minneapolis, MN 55427

Pyrethrum Board of Kenya Nakuru, Kenya

S.C. Johnson & Son, Inc. Racine, WI 53403

From: Owen Caine [ocaine@cspa.org]
Sent: 11/22/2017 6:43:52 PM

To: Keller, Kaitlin [keller.kaitlin@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

CC: Hanley, Mary [Hanley.Mary@epa.gov]; Cassandra LaRussa [clarussa@cspa.org]

Subject: Re: CSPA Annual Meeting

Sound great. Will send over the info next week.

Sent from my Verizon LG Smartphone

----- Original message-----From: Keller, Kaitlin

Date: Wed, Nov 22, 2017 1:40 PM
To: Owen Caine; Beck, Nancy;
Cc: Hanley, Mary; Cassandra LaRussa;
Subject: RE: CSPA Annual Meeting

Hi Owen,

Let's do 10am on 11/30. Please send me the WebEx info to connect with when you get a chance. Hope everyone has a nice Thanksgiving.

Thanks, Kaitlin

Kaitlin Keller, Special Assistant Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency (202) 564-7098

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 1:53 PM

To: Keller, Kaitlin < keller.kaitlin@epa.gov>; Beck, Nancy < Beck.Nancy@epa.gov> **Cc:** Hanley, Mary < Hanley.Mary@epa.gov>; Cassandra LaRussa < clarussa@cspa.org>

Subject: RE: CSPA Annual Meeting

Hey Kaitlin,

We are free that whole morning. Just let us know when would work best for you and we will add it to our calendar. Thank you for all the help!

-Owen

From: Keller, Kaitlin [mailto:keller.kaitlin@epa.gov]

Sent: Tuesday, November 21, 2017 1:41 PM

To: Owen Caine <ocaine@cspa.org>; Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Hanley, Mary < Hanley, Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Owen,

I'll be setting up for Nancy on the 4th, so for the dry run next week it will likely just be with me. Please let me know if Thursday morning works for you and/or your staff.

Thanks, Kaitlin

From: Keller, Kaitlin

Sent: Tuesday, November 21, 2017 1:32 PM

To: 'Owen Caine' <ocaine@cspa.org>; Beck, Nancy <beck.nancy@epa.gov>

Cc: Hanley, Mary < Hanley, Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Hello Owen,

Nancy is available between 9:30am-12:30pm on Thursday, November 30th. Is there a half an hour within that window that works for you?

Thanks, Kaitlin

Kaitlin Keller, Special Assistant Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency (202) 564-7098

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 12:32 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Keller, Kaitlin < keller.kaitlin@epa.gov>; Hanley, Mary < Hanley.Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Thanks Nancy. That sounds great. We can certainly make the Webex video work. We are pretty open next week for a trial, so just let us know a couple times that work for you and we will adjust our schedule accordingly.

In terms of the slides. The topic areas I would suggest would be:

- The PMN "backlog" and efforts to reduce it
- PRIA implementation
- TSCA implementation

That said, I am sure my members would be eager to hear about your priorities moving forward, accomplishments from the EPA in our areas, etc. Basically meaning you should feel free to talk about whatever you want. Also, there will be no press in the room and the session is not recorded by CSPA in any way. The session starts at 11:45am on Monday, December 4th and you would be the first speaker. As I said, I was thinking around 25 minutes, plus a couple questions. Please let me know if you have any other questions.

-Owen

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, November 21, 2017 12:11 PM

To: Owen Caine < ocaine@cspa.org >

Cc: Keller, Kaitlin < keller.kaitlin@epa.gov >; Hanley, Mary < Hanley.Mary@epa.gov >

Subject: RE: CSPA Annual Meeting

Owen,

While we cant initiate a Webex we think we can join one so that approach would work. Can we perhaps do a practice next week with some of your staff to make sure we can get this to work?

If it does work I will plan on providing some slides. Can you remind me again of the exact time of the session and the topics--should it be existing chemicals, new chemicals, inventory rule, and PRIA?

Thanks for the flexibility.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

M: Personal Phone / Ex. 6

beck.nancy@epa.gov

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 9:43 AM
To: Beck, Nancy < Beck. Nancy@epa.gov >

Subject: CSPA Annual Meeting

Hey Nancy,

Good talking with you yesterday. I spoke with my meetings director this morning and we have three potential solutions for you, understanding that it would be a lot of travel for you in a very busy time. Our preferences would be:

- If there is someone else, either who is already going or someone new, who works for you who could take your place at the meeting and talk about the EPA's plans moving forward, we could do that.
- We have access to both WebX and Zoom video conferencing, which would allow you to give your speech from EPA to the meeting in Florida. I just don't know the technological resources you have available to you at EPA on short notice.
- You could easily just call in and talk to the group on the phone.

Let me know your thoughts. I am happy to work through any issues to make it work.

Many thanks!

Owen Caine

Executive Vice President
Government Relations & Public Policy



"Representing Household & Institutional Products"

Consumer Specialty Products Association

1667 K Street NW, Suite 300 | Washington, DC 20006 Direct: 202-833-7310 - Office: 202-872-8110 ocaine@cspa.org | www.cspa.org

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From: Steven D. Bennett [sbennett@cspa.org]

Sent: 11/28/2017 2:25:26 PM

To: Goodis, Michael [Goodis.Michael@epa.gov]

CC: Keigwin, Richard [Keigwin.Richard@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Concerns with Adequacy of Efficacy Data

Attachments: efficacycspafinal.pdf

Importance: High

Michael,

On behalf of the CSPA, please see the attached letter on an issue of significant importance to many of members related to recent letters about the adequacy of efficacy data.

We would also like to discuss this in-person next week while in attendance at the CSPA Annual Meeting.

Thank for your time and we look forward to discussing this issue in more detail.

Steven Bennett, Ph.D.

Vice President of Scientific Affairs
Pest Management Products Division Staff
Executive
Polishes & Floor Maintenance Division Staff
Executive



"Representing Household & Institutional Products"

Consumer Specialty Products Association

1667 K Street NW, Suite 300 | Washington, DC 20006 Direct: 202-833-7330 - Office: 202-872-8110 <u>sbennett@cspa.org</u> | <u>www.cspa.org</u>

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November 16, 2017

Michael L. Goodis, Registration Division (7505P) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001

Mr. Goodis,

There is an issue of significant importance to many of members that I would like to bring to your attention related to adequacy of efficacy data. Numerous companies have received letters from the Registration Division requesting either they generate efficacy data before the Agency has revised its efficacy guidelines or remove public health pests claims from the associated labels.

As part of product reregistration, companies generated and submitted to EPA efficacy data related to a range of products sold by CSPA member companies which include active ingredients such as pyrethrins, piperonyl butoxide and others. Companies submitted these data to EPA pursuant to Product Data Call Ins (PDCIs) as far back as 2007 and generally by 2011. Most companies did not receive reviews of this data from EPA on these submissions until recently, upwards of 10 years after the data was submitted. In the interim, EPA has committed to revise its efficacy guidelines but has yet to do so. The reviews which companies have received related to studies generated a decade ago have identified deficiencies not related to the guidelines in place at the time but related to what is now considered by EPA to be the likely guidelines that are forthcoming. This approach is inappropriate and should be reconsidered. Putting aside the failure to review these data in a timely manner, these studies should be evaluated against the standards in place at the time the data was required. The matter is further exacerbated by EPA's requirement of companies to generate new data against standards that have not been established.

Furthermore, this approach is also being used to re-review data on file with the Agency to support claims on currently registered products and pending follow-on me-too products. The re-reviews are finding deficiencies in studies based on current internal efficacy standards, when the previously acceptable studies met guidelines in place at the time of the original registration or multiple subsequent reviews.

From our perspective, the most rationale, equitable and sound manner to approach this issue is for EPA to issue draft efficacy guidelines, receive comment and peer review on said

guidelines, finalize the guidelines and then follow up where appropriate with DCIs as part of the registration or registration review processes. In the meantime, it would be most advantageous to all that until the above is completed that the EPA refrain from reassessing existing studies and requesting changes to existing labels.

Finally, it is important to note that our members are very confident of the efficacy of these products. Although the existing guidelines should be updated, current studies are not without value especially considering that we also have many years of field experience with these products that support their efficacy.

Sincerely,

Steven Bennett, Ph.D.

Vice President of Scientific Affairs

Consumer Specialty Products Association

Cc: Rick Keigwin, Director, Office of Pesticide Programs

Nancy Beck, Ph.D., Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention

From: Cassandra LaRussa [clarussa@cspa.org]

Sent: 11/27/2017 7:01:19 PM

To: Keller, Kaitlin [keller.kaitlin@epa.gov]; Owen Caine [ocaine@cspa.org]; Beck, Nancy [Beck.Nancy@epa.gov]

CC: Hanley, Mary [Hanley.Mary@epa.gov]

Subject: RE: CSPA Annual Meeting

Great - thanks Kaitlin!

I just sent this info over, so should you receive it shortly. On Thursday, please use the 'panelist' link to log in.

If you have any other questions, please let me know!

Best,

Cassy

Cassandra LaRussa

Director, Meetings & Conventions



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From: Keller, Kaitlin [mailto:keller.kaitlin@epa.gov] Sent: Wednesday, November 22, 2017 1:40 PM

To: Owen Caine <ocaine@cspa.org>; Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Hanley, Mary <Hanley.Mary@epa.gov>; Cassandra LaRussa <clarussa@cspa.org>

Subject: RE: CSPA Annual Meeting

Hi Owen,

Let's do 10am on 11/30. Please send me the WebEx info to connect with when you get a chance. Hope everyone has a nice Thanksgiving.

Thanks, Kaitlin

Kaitlin Keller, Special Assistant Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency (202) 564-7098

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 1:53 PM

To: Keller, Kaitlin < keller.kaitlin@epa.gov>; Beck, Nancy < Beck.Nancy@epa.gov> **Cc:** Hanley, Mary < Hanley.Mary@epa.gov>; Cassandra LaRussa < clarussa@cspa.org>

Subject: RE: CSPA Annual Meeting

Hey Kaitlin,

We are free that whole morning. Just let us know when would work best for you and we will add it to our calendar. Thank you for all the help!

-Owen

From: Keller, Kaitlin [mailto:keller.kaitlin@epa.gov]

Sent: Tuesday, November 21, 2017 1:41 PM

To: Owen Caine <ocaine@cspa.org>; Beck, Nancy <Beck.Nancy@epa.gov>

Cc: Hanley, Mary < Hanley. Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Owen,

I'll be setting up for Nancy on the 4th, so for the dry run next week it will likely just be with me. Please let me know if Thursday morning works for you and/or your staff.

Thanks, Kaitlin

From: Keller, Kaitlin

Sent: Tuesday, November 21, 2017 1:32 PM

To: 'Owen Caine' <ocaine@cspa.org>; Beck, Nancy <beck.nancy@epa.gov>

Cc: Hanley, Mary < Hanley, Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Hello Owen,

Nancy is available between 9:30am-12:30pm on Thursday, November 30th. Is there a half an hour within that window that works for you?

Thanks, Kaitlin Kaitlin Keller, Special Assistant Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency (202) 564-7098

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 12:32 PM
To: Beck, Nancy < Beck, Nancy@epa.gov>

Cc: Keller, Kaitlin < keller.kaitlin@epa.gov >; Hanley, Mary < Hanley.Mary@epa.gov >

Subject: RE: CSPA Annual Meeting

Thanks Nancy. That sounds great. We can certainly make the Webex video work. We are pretty open next week for a trial, so just let us know a couple times that work for you and we will adjust our schedule accordingly.

In terms of the slides. The topic areas I would suggest would be:

- The PMN "backlog" and efforts to reduce it
- PRIA implementation
- TSCA implementation

That said, I am sure my members would be eager to hear about your priorities moving forward, accomplishments from the EPA in our areas, etc. Basically meaning you should feel free to talk about whatever you want. Also, there will be no press in the room and the session is not recorded by CSPA in any way. The session starts at 11:45am on Monday, December 4th and you would be the first speaker. As I said, I was thinking around 25 minutes, plus a couple questions. Please let me know if you have any other questions.

-Owen

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, November 21, 2017 12:11 PM

To: Owen Caine <ocaine@cspa.org>

Cc: Keller, Kaitlin < keller.kaitlin@epa.gov>; Hanley, Mary < Hanley.Mary@epa.gov>

Subject: RE: CSPA Annual Meeting

Owen,

While we cant initiate a Webex we think we can join one so that approach would work. Can we perhaps do a practice next week with some of your staff to make sure we can get this to work?

If it does work I will plan on providing some slides. Can you remind me again of the exact time of the session and the topics--should it be existing chemicals, new chemicals, inventory rule, and PRIA?

Thanks for the flexibility.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Owen Caine [mailto:ocaine@cspa.org]
Sent: Tuesday, November 21, 2017 9:43 AM

To: Beck, Nancy < Beck. Nancy@epa.gov > Subject: CSPA Annual Meeting

Hey Nancy,

Good talking with you yesterday. I spoke with my meetings director this morning and we have three potential solutions for you, understanding that it would be a lot of travel for you in a very busy time. Our preferences would be:

- If there is someone else, either who is already going or someone new, who works for you who could take your place at the meeting and talk about the EPA's plans moving forward, we could do that.
- We have access to both WebX and Zoom video conferencing, which would allow you to give your speech from EPA to the meeting in Florida. I just don't know the technological resources you have available to you at EPA on short notice.
- You could easily just call in and talk to the group on the phone.

Let me know your thoughts. I am happy to work through any issues to make it work.

Many thanks!

Owen Caine

Executive Vice President
Government Relations & Public Policy



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From: Cassandra LaRussa [clarussa@cspa.org]

Sent: 11/8/2017 2:59:59 PM

To: Marshall, Venus [Marshall.Venus@epa.gov]

CC: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

CSPA will take care of the hotel room - I will make a reservation on behalf of Nancy and put it on our Master List.

For the travel – it will probably be easier if we reimburse you, as you will be able to make the flight reservation easier, given you know Nancy's schedule and travel info.

Thanks, Cassy

From: Marshall, Venus [mailto:Marshall.Venus@epa.gov]

Sent: Wednesday, November 8, 2017 9:28 AM **To:** Cassandra LaRussa <clarussa@cspa.org> **Cc:** Beck, Nancy <Beck.Nancy@epa.gov>

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

Hi Cassandra,

Will CSPA be paying the expenses up front or will CSPA be reimbursing EPA for the costs of the travel and hotel.

Thanks,

Venus Marshall
Office of the Assistant Administrator
Office of Chemical Safety and Pollution Prevention, OCSPP
Room 3130 - EPA East, MC 7101M

Phone: 202-564-8542 Fax: 202-564-0801 marshall.venus@epa.gov

From: Cassandra LaRussa [mailto:clarussa@cspa.org]
Sent: Wednesday, November 08, 2017 9:12 AM
To: Marshall, Venus < Marshall, Venus@epa.gov>

Cc: Beck, Nancy < Beck. Nancy@epa.gov>

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

Hi Venus,

Yes - CSPA will cover travel and hotel room.

Let me know if there is anything else!

Best, Cassy From: Marshall, Venus [mailto:Marshall.Venus@epa.gov]

Sent: Wednesday, November 8, 2017 8:06 AM **To:** Cassandra LaRussa <<u>clarussa@cspa.org</u>> **Cc:** Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

Hi Cassandra,

Personal Address / Ex. 6

The CSPA stated in the invitation that they were willing to cover the cost of the travel and lodging for this event. Cassandra, please confirm if the CSPA is still willing to pay for the lodging and the travel. This info is needed for me so I can properly prepare the travel authorization.

Thanks,

Venus Marshall
Office of the Assistant Administrator
Office of Chemical Safety and Pollution Prevention, OCSPP
Room 3130 - EPA East, MC 7101M

Phone: 202-564-8542
Fax: 202-564-0801
marshall.venus@epa.gov

From: Cassandra LaRussa [mailto:clarussa@cspa.org]

Sent: Monday, November 06, 2017 1:38 PM **To:** Marshall, Venus < <u>Marshall, Venus@epa.gov</u>>

Subject: CSPA Annual Meeting: Nancy Beck Registration

Hi Marshall,

In follow up to our conversation this morning, I just registered Nancy for the meeting. You should see that confirmation come through shortly.

I'm happy to make a hotel reservation on her behalf as well – at the government rate – if you let me know when she is checking in and checking out.

Best, Cassy

Cassandra LaRussa

Director, Meetings & Conventions



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From: Cassandra LaRussa [clarussa@cspa.org]

Sent: 11/6/2017 7:14:34 PM

To: Marshall, Venus [Marshall.Venus@epa.gov]

CC: Hanley, Mary [Hanley.Mary@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

Great - thanks!

From: Marshall, Venus [mailto:Marshall.Venus@epa.gov]

Sent: Monday, November 6, 2017 2:10 PM **To:** Cassandra LaRussa <clarussa@cspa.org>

Cc: Hanley, Mary <Hanley.Mary@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>

Subject: RE: CSPA Annual Meeting: Nancy Beck Registration

Hi Cassandra,

Once Nancy confirms with me which dates she would like to travel, I'll get back with you on the details and we can finalize hotel reservations as to when she wants to check in and check out.

Thanks,

Venus Marshall
Office of the Assistant Administrator
Office of Chemical Safety and Pollution Prevention, OCSPP
Room 3130 - EPA East, MC 7101M

Phone: 202-564-8542 Fax: 202-564-0801 marshall.venus@epa.gov

From: Cassandra LaRussa [mailto:clarussa@cspa.org]

Sent: Monday, November 06, 2017 1:38 PM **To:** Marshall, Venus < Marshall, Venus @epa.gov>

Subject: CSPA Annual Meeting: Nancy Beck Registration

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Best,

Cassy

Cassandra LaRussa

Director, Meetings & Conventions



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From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 11/15/2017 4:50:32 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]
CC: Bolen, Derrick [bolen.derrick@epa.gov]

Subject: RE: PMN meeting

Thanks, Nancy – let me collect a bit more specific information to address your note below and will be back in touch with you and Derek.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Wednesday, November 15, 2017 9:00 AM
To: Juberg, Daland (DR) < DRJuberg@dow.com>
Cc: Bolen, Derrick < bolen.derrick@epa.gov>

Subject: PMN meeting

Daland,

Got your message and I presume you are referring to a new chemical issue. Happy to have a 30 minute meeting (phone or in person). Derek can help get it on my calendar and if you tell me or him the PMN number we can ensure correct experts attend as well. You may not want to email the PMN number as it may likely be CBI.

If you were referring to something else, just let me know the topic.

Regards, Nancy

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Owen Caine [ocaine@cspa.org]

Sent: 11/1/2017 7:25:21 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Time to meet

Hey Nancy,

Once again, we are very excited to have you down in Florida. On an unrelated note, I was wondering if you might have 10-15 minutes some time in the next week or so to briefly meet in person and talk through just one or two issues for CSPA. I am more than happy to work around your schedule. The only day that don't work for me are the 13th and 14th. Please let me know what might work for you.

Many thanks!

Owen Caine

Executive Vice President
Government Relations & Public Policy



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From: Richard E. Engler, Ph.D. [rengler@lawbc.com]

Sent: 10/16/2017 12:27:37 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]; mwhittaker@toxservices.com

CC: Jennifer Tanir [jentanir@gmail.com]; jsass@nrdc.org; Devito, Steve [Devito.Steve@epa.gov]; Henry, Tala

[Henry.Tala@epa.gov]; Kimberly_White@americanchemistry.com; bobsussman1@comcast.net; Ashley Black

[ashley@toxicology.org]

Subject: RE: Thanks to each of you--Oct 13 NCAC/CSW symposium

Thank you for giving us an opportunity to discuss some of these critical issues and places where we agree and disagree!

Rich

RICHARD E. ENGLER, PH.D. SENIOR CHEMIST

BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3808 | F: 202-557-3836 | lawbe.com

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, October 13, 2017 7:01 PM

To: mwhittaker@toxservices.com

Cc: Jennifer Tanir; Richard E. Engler, Ph.D.; jsass@nrdc.org; Devito, Steve; Henry, Tala; Kimberly_White@americanchemistry.com; bobsussman1@comcast.net; Ashley Black

Subject: Re: Thanks to each of you--Oct 13 NCAC/CSW symposium

Meg,

Thanks to you and NCAC/ACS team for putting together such a nice program. I only wish I could have stayed for the full day.

I hope it was a success and I look forward to further dialogue-- it's important for the success of our programs.

Regards,

Nancy.

Nancy B. Beck, Ph.D., DABT

Denuty Assistant Administrator OCSPP

Personal Address / Ex. 6

Beck.Nancy@epa.gov

On Oct 13, 2017, at 6:22 PM, Margaret Whittaker < Mwhittaker@toxservices.com > wrote:

Thanks to everyone for presenting at today's symposium. I am very appreciative of the time that each of you took to prepare and participate.

I hope everyone has a nice weekend!

Sincerely,

Meg

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T.

Managing Director and Chief Toxicologist ToxServices LLC 1367 Connecticut Avenue, N.W., Suite 300 Washington, D.C. 20036 (202) 429-8787 (US telephone) +44(0) 20 3318 3429 (UK telephone) (202) 429-8788 (fax) www.toxservices.com

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From: Jennifer Tanir [mailto:jentanir@gmail.com]
Sent: Thursday, October 12, 2017 12:03 PM

To: beck.nancy@epa.gov; Richard E. Engler, Ph.D. < rengler@lawbc.com >; jsass@nrdc.org; Steve Devito

<Devito.Steve@epa.gov>; Henry.Tala@epa.gov; Kimberly White@americanchemistry.com;

bobsussman1@comcast.net

Cc: Margaret Whittaker < Mwhittaker@toxservices.com; Ashley Black < ashley@toxicology.org

Subject: Re: Important details about Oct 13 NCAC/CSW symposium

Dear Presenters,

Please send me your presentations, short bios, and SOT permission form (attached) by this afternoon. The attached table summarizes the materials I've received so far.

Tomorrow's program starts early, so we would like to have everything in place by later today. Also, SOT will be running and recording a live webinar during the symposium, so we need to make sure we have the permissions in place in advance.

If you have any questions, please don't hesitate to contact me anytime! My cell is 202-258-7951. It should be an excellent symposium!

Thanks, Jen

Jennifer Y. Tanir, PhD CSW Secretary

On Fri, Oct 6, 2017 at 9:36 AM, Jennifer Tanir < ientanir@gmail.com > wrote:

I knew I would forget something! I meant to also ask you to send a **short bio** with your slides, so we can properly introduce you. Meg and I know who you are, but a few sentences will help us get the details right, and can avoid Meg telling some embarrassing story about you:)

Thanks! Jen

On Fri, Oct 6, 2017 at 8:18 AM, Jennifer Tanir < jentanir@gmail.com> wrote: Dear presenters,

Our symposium is just a week away! Thank you so much for agreeing to participate. I have a few deadlines and details to let you know about:

Presentations: please provide your presentation to me by **Wednesday, October 11**. The reason is that we are running a webinar of the symposium from SOT headquarters during the live event at ACS headquarters, so we need to copies in both places and make sure they're working. If you have trouble meeting this deadline, please let me know.

Permission: please **fill in and return** the attached SOT permission form regarding release of your materials. The webinar will be recorded and posted on the SOT website, along with the slides, pending your permission. If you have questions, please contact Ashley Black at SOT (cc'ed).

Agenda: the final symposium agenda is located

here: https://www.toxicology.org/groups/rc/ncac/docs/NCAC CSW Fall 2017 Symposium Final Age nda.pdf.

Registration: you've all been registered for the meeting and received a confirmation email yesterday. Lunch and breaks are included (but no breakfast).

Numbers/Set-up: as of yesterday, we have 50+ people registered to attend in person and 40+ registered for the online webinar. The limit in the room will be about 75 people (set 6-8 people around tables). The room is a long rectangle, with stage, podium, microphone, and large screen for your presentation, and additional TV screens towards the back of the room for viewing of the slides. In a side room, we'll have 24 posters by students & postdocs during the poster competition. We'll take questions from the "chat window" of the webinar too, during the Q&A periods.

Please let me or Meg know if you have any questions as you prepare for the symposium!

Best, Jen

Jennifer Y. Tanir, PhD CSW Secretary (202) 258-7951

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From: Henry, Tala [Henry.Tala@epa.gov]

Sent: 10/14/2017 3:53:11 PM

To: Devito, Steve [Devito.Steve@epa.gov]; mwhittaker@toxservices.com

CC: Jennifer Tanir [jentanir@gmail.com]; Beck, Nancy [Beck.Nancy@epa.gov]; Richard E. Engler, Ph.D.

[rengler@lawbc.com]; jsass@nrdc.org; Kimberly_White@americanchemistry.com; bobsussman1@comcast.net;

Ashley Black [ashley@toxicology.org]

Subject: RE: Thanks to each of you--Oct 13 NCAC/CSW symposium

A day later...but still, I concur with all others, it was an excellent program and the panel Q&A and discussion was very helpful, I think, in message out for us and hopefully providing more clarity about how things fit together for the attendees.

Thanks again for the invite!

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959 E: henry.tala@epa.gov

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bobsussman1@comcast.net; Ashley Black <ashley@toxicology.org> **Subject:** Re: Thanks to each of you--Oct 13 NCAC/CSW symposium

Meg:

Thank you. My compliments to you on organizing such well-rounded meeting. It was a pleasure to be a part of it.

Sincerely, Steve DeVito

Sent from my iPhone

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Managing Director and Chief Toxicologist ToxServices LLC 1367 Connecticut Avenue, N.W., Suite 300 Washington, D.C. 20036 (202) 429-8787 (US telephone) +44(0) 20 3318 3429 (UK telephone) (202) 429-8788 (fax) www.toxservices.com

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<<u>Devito.Steve@epa.gov</u>>; <u>Henry.Tala@epa.gov</u>; <u>Kimberly_White@americanchemistry.com</u>;

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Cc: Margaret Whittaker < Mwhittaker@toxservices.com; Ashley Black < ashley@toxicology.org>

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From: White, Kimberly [Kimberly_White@americanchemistry.com]

Sent: 10/13/2017 11:08:04 PM

To: mwhittaker@toxservices.com; Jennifer Tanir [jentanir@gmail.com]; Beck, Nancy [Beck.Nancy@epa.gov]; Richard E.

Engler, Ph.D. [rengler@lawbc.com]; jsass@nrdc.org; Devito, Steve [Devito.Steve@epa.gov]; Henry, Tala

[Henry.Tala@epa.gov]; bobsussman1@comcast.net

CC: Ashley Black [ashley@toxicology.org]

Subject: Re: Thanks to each of you--Oct 13 NCAC/CSW symposium

Thank you Meg, ACS and NCAC for putting together the session and inviting me to join. It was a good discussion.

----- Original Message -----

Subject: Thanks to each of you--Oct 13 NCAC/CSW symposium

From: Margaret Whittaker Mwhittaker@toxservices.com

Date: Oct 13, 2017, 6:21 PM

To: Jennifer Tanir <jentanir@gmail.com>,beck.nancy@epa.gov,"Richard E. Engler, Ph.D."

<rengler@lawbc.com>,jsass@nrdc.org,Steve Devito <Devito.Steve@epa.gov>,Henry.Tala@epa.gov,"White,

Kimberly" < Kimberly White@americanchemistry.com>,bobsussman1@comcast.net

Thanks to everyone for presenting at today's symposium. I am very appreciative of the time that each of you took to prepare and participate.

I hope everyone has a nice weekend!

Sincerely,

Meg

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T.

Managing Director and Chief Toxicologist

ToxServices LLC

1367 Connecticut Avenue, N.W., Suite 300

Washington, D.C. 20036

(202) 429-8787 (US telephone)

+44(0) 20 3318 3429 (UK telephone)

(202) 429-8788 (fax)

www.toxservices.com

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From: Jennifer Tanir [mailto:jentanir@gmail.com]

Sent: Thursday, October 12, 2017 12:03 PM

To: beck.nancy@epa.gov; Richard E. Engler, Ph.D. <rengler@lawbc.com>; jsass@nrdc.org; Steve Devito <Devito.Steve@epa.gov>; Henry.Tala@epa.gov; Kimberly_White@americanchemistry.com; bobsussman1@comcast.net

betho.steve@epa.gov>, frem y.rala@epa.gov, kimberry_vvinte@americanenemistry.com, bobsassmanie@comeast.ne

Cc: Margaret Whittaker < Mwhittaker@toxservices.com>; Ashley Black < ashley@toxicology.org> **Subject:** Re: Important details about Oct 13 NCAC/CSW symposium

Dear Presenters,

Please send me your presentations, short bios, and SOT permission form (attached) by this afternoon. The attached table summarizes the materials I've received so far.

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If you have any questions, please don't hesitate to contact me anytime! My cell is 202-258-7951. It should be an excellent symposium!

Thanks, Jen

Jennifer Y. Tanir, PhD CSW Secretary

On Fri, Oct 6, 2017 at 9:36 AM, Jennifer Tanir < jentanir@gmail.com > wrote:

I knew I would forget something! I meant to also ask you to send a **short bio** with your slides, so we can properly introduce you. Meg and I know who you are, but a few sentences will help us get the details right, and can avoid Meg telling some embarrassing story about you:)

Thanks! Jen

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Please let me or Meg know if you have any questions as you prepare for the symposium!

Best, Jen

Jennifer Y. Tanir, PhD CSW Secretary (202) 258-7951

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From: Jennifer Tanir [jentanir@gmail.com]

Sent: 10/16/2017 2:10:18 PM

To: Richard E. Engler, Ph.D. [rengler@lawbc.com]

CC: Beck, Nancy [Beck.Nancy@epa.gov]; mwhittaker@toxservices.com; jsass@nrdc.org; Devito, Steve

[Devito.Steve@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kimberly_White@americanchemistry.com;

bobsussman1@comcast.net; Ashley Black [ashley@toxicology.org]

Subject: Re: Thanks to each of you--Oct 13 NCAC/CSW symposium

I echo Meg's sentiments - thank you all for your time and active participation! I learned a lot from the excellent presentations and discussions. And that most of the participants in the room and on the webinar stayed until the end was a testament to their interest!

Best, Jen

Jennifer Y. Tanir, PhD Founder and Consultant Toward Safer LLC <u>jentanir@towardsafer.com</u> www.towardsafer.com

On Sun, Oct 15, 2017 at 8:27 PM, Richard E. Engler, Ph.D. rengler@lawbc.com wrote:

Thank you for giving us an opportunity to discuss some of these critical issues and places where we agree and disagree!

Rich

RICHARD E. ENGLER, PH.D.

SENIOR CHEMIST

BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037

T: <u>202-557-3808</u> | F: <u>202-557-3836</u> | lawbe.com

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, October 13, 2017 7:01 PM

To: mwhittaker@toxservices.com

Cc: Jennifer Tanir; Richard E. Engler, Ph.D.; <u>jsass@nrdc.org</u>; Devito, Steve; Henry, Tala; <u>Kimberly White@americanchemistry.com</u>; <u>bobsussman1@comcast.net</u>; Ashley Black

Subject: Re: Thanks to each of you--Oct 13 NCAC/CSW symposium

Meg, Thanks to you and NCAC/ACS team for putting together such a nice program. I only wish I could have stayed for the full day. I hope it was a success and I look forward to further dialogue—it's important for the success of our programs. Regards, Nancy. Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP Personal Address / Ex. 6 Beck.Nancy@epa.gov On Oct 13, 2017, at 6:22 PM, Margaret Whittaker < <u>Mwhittaker@toxservices.com</u>> wrote: Thanks to everyone for presenting at today's symposium. I am very appreciative of the time that each of you took to prepare and participate. I hope everyone has a nice weekend! Sincerely, Meg

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T.

Managing Director and Chief Toxicologist ToxServices LLC

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(202) 429-8787 (US telephone)
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Find us on Facebook! <image001.gif> From: Jennifer Tanir [mailto:jentanir@gmail.com] Sent: Thursday, October 12, 2017 12:03 PM To: beck.nancy@epa.gov; Richard E. Engler, Ph.D. <rengler@lawbc.com>; jsass@nrdc.org; Steve Devito < Devito. Steve@epa.gov>; Henry. Tala@epa.gov; Kimberly White@americanchemistry.com; bobsussman1@comcast.net Cc: Margaret Whittaker < Mwhittaker @toxservices.com >; Ashley Black <ashley@toxicology.org> Subject: Re: Important details about Oct 13 NCAC/CSW symposium Dear Presenters, Please send me your presentations, short bios, and SOT permission form (attached) by this afternoon. The attached table summarizes the materials I've received so far Tomorrow's program starts early, so we would like to have everything in place by later today. Also, SOT will be running and recording a live webinar during the symposium, so we need to make sure we have the permissions in place in advance.

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CSW Secretary

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(202) 258-7951

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From: Jennifer Tanir [jentanir@gmail.com]

Sent: 10/12/2017 4:02:31 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]; jsass@nrdc.org; Devito, Steve

[Devito.Steve@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kimberly_White@americanchemistry.com;

bobsussman1@comcast.net

CC: mwhittaker@toxservices.com; Ashley Black [ashley@toxicology.org]

Subject: Re: Important details about Oct 13 NCAC/CSW symposium

Attachments: Permissions Release for SOT Use of Materials.pdf; Tracking presenter files.xlsx

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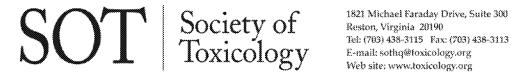
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Web site: www.toxicology.org

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Return completed and signed form to SOT Attention: Tierre Miller 1821 Michael Faraday Drive Suite 300 Reston, Virginia 20190 FAX: 703 438-3113 or PDF to tierre@toxicology.org

Rev. 7/22/11

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Presenter	Bio	Slides	form
Nancy Beck		Yes	
Richard Engler			
Jennifer Sass &			
Bob Sussman	Yes		
Stephen DeVito			(Yes)
Tala Henry			
Kimberly White	Yes	Yes	

From: Margaret Whittaker [Mwhittaker@toxservices.com]

Sent: 10/6/2017 2:23:18 PM

To: Richard E. Engler, Ph.D. [rengler@lawbc.com]; 'Jennifer Tanir' [jentanir@gmail.com]; Beck, Nancy

[Beck.Nancy@epa.gov]; jsass@nrdc.org; Devito, Steve [Devito.Steve@epa.gov]; Henry, Tala [Henry.Tala@epa.gov];

Kimberly_White@americanchemistry.com

CC: Ashley Black [ashley@toxicology.org]

Subject: RE: Important details about Oct 13 NCAC/CSW symposium

Yes! You go first 😊

Meg

Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T.

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From: Richard E. Engler, Ph.D. [mailto:rengler@lawbc.com]

Sent: Friday, October 06, 2017 10:22 AM

To: 'Jennifer Tanir' <jentanir@gmail.com>; beck.nancy@epa.gov; jsass@nrdc.org; Devito.Steve@epa.gov;

Henry.Tala@epa.gov; Kimberly White@americanchemistry.com

Cc: Margaret Whittaker <Mwhittaker@toxservices.com>; Ashley Black <ashley@toxicology.org>

Subject: RE: Important details about Oct 13 NCAC/CSW symposium

Can we get the embarrassing stories during the break?

RICHARD E. ENGLER, PH.D. SENIOR CHEMIST

DEFICION CHEMISI

BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3808 | F: 202-557-3836 | lawbe.com

From: Jennifer Tanir [mailto:jentanir@gmail.com]

Sent: Friday, October 06, 2017 9:37 AM

To: beck.nancy@epa.gov; Richard E. Engler, Ph.D.; jsass@nrdc.org; Devito.Steve@epa.gov; Henry.Tala@epa.gov;

Kimberly White@americanchemistry.com

Cc: Margaret Whittaker; Ashley Black

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From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 10/10/2017 2:28:28 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: FW: IPSA

FYI – on a new role I am taking on...

From: Juberg, Daland (DR)

Sent: Tuesday, October 10, 2017 10:01 AM

To: Dourson, Michael (doursoml) <doursoml@ucmail.uc.edu>

Cc: 'nancy.beck@epa.gov' <nancy.beck@epa.gov>

Subject: IPSA

Hi Mike – Have you made any more traction with the idea for an Institute of Predictive Safety Assessment? I am going to move from leading the global human health assessment team to leading the Human Health Science Policy at Dow/Dupont – new position – that I will create/design/roll-out – Part of this will be identifying those science initiatives where multiple stakeholders have an interest in shaping/moving forward – let me know current status of this and let's talk down the road on areas where EPA might have interest in moving the needle.

Daland

From: Jennifer Tanir [jentanir@gmail.com]

Sent: 10/6/2017 1:36:37 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]; Richard E. Engler, Ph.D. [rengler@lawbc.com]; jsass@nrdc.org; Devito, Steve

[Devito.Steve@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kimberly_White@americanchemistry.com

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From: Liu, Andrew H [ANDREW.H.LIU@chemours.com]

Sent: 9/20/2017 4:07:11 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: Greetings!

Sensitivity: Private

Will do!

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov] **Sent:** Wednesday, September 20, 2017 11:12 AM **To:** Liu, Andrew H < ANDREW.H.LIU@chemours.com>

Subject: RE: Greetings! **Sensitivity:** Private

Nonresponsive Discussion of Personal Matters / Ex. 6

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Liu, Andrew H [mailto:ANDREW.H.LIU@chemours.com]

Sent: Wednesday, September 20, 2017 10:09 AM

To: Beck, Nancy < Beck. Nancy@epa.gov >

Subject: RE: Greetings! **Sensitivity:** Private

Me too, Nancy. DC has so much more to offer than Wilmington.

What's your schedule like between Thanksgiving and Christmas? If too busy during the holiday season, perhaps we can try January?

Andy

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Wednesday, September 20, 2017 10:04 AM
To: Liu, Andrew H < ANDREW.H.LIU@chemours.com>

Subject: RE: Greetings! **Sensitivity:** Private

Thanks Andy,

I haven't heard much but I will check with our international group to see if this aligns with what they know.

Nonresponsive Discussion of Personal Matters / Ex. 6

Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP

P: 202-564-1273 M: 202-731-9910 beck.nancy@epa.gov

From: Liu, Andrew H [mailto:ANDREW.H.LIU@chemours.com]

Sent: Wednesday, September 20, 2017 9:52 AM

To: Beck, Nancy < Beck. Nancy@epa.gov >

Subject: RE: Greetings! **Sensitivity:** Private

Hi Nancy,

Hope your week is going well!

Here is what I have heard. Sorry if there's redundant information you already know.

I assume SAHTECH has been the people contacting you? As you know, they are a semi-governmental organization (http://www.sahtech.org/content/en/sahtech/About.aspx). Taiwan Environmental Protection Administration (EPA) contract services from SAHTECH for technical support. Dr. Li is a key leader and the main outward-facing representative for the organization. SAHTECH participates heavily in international meetings to represent Chinese Taipei.

I understand that SAHTECH has submitted a revised agenda to Taiwan EPA for approval before sending to you.

The main government sponsor is the Taiwan EPA Toxic Chemical Substance Bureau who has responsibility to implement the Toxic Chemical and Substances Control Act (TCSCA), but the opening will likely be by someone on the ministerial level. This is an important timing for Taiwan EPA because their New Chemicals program has started recently and their existing chemicals program is drafted, but not finalized. They are no longer simply implementing their version of REACH, like Korea. They are focusing their resources on the draft list of the initial 122 substances. And they are building flexibility in the data generation/requirements.

I am told that they are very interested in US EPA experience under TSCA and LCSA, such as changes, progress, status, lessons, stakeholder input/expectations, challenges. I think they are also interested in past experiences, such as the Work Plan.

My understanding is that you'll be the keynote speaker, followed by representatives from EU, Korea and Vietnam. It seems the second day will include additional words from you, followed by a panel discussion with Q/A, and an industry section in the afternoon. There may be a change of location to the Taiwan EPA offices for discussion among the regulators after the public forum.

Industry participation will be mostly by multinational companies, AMCHAM, and Taiwan Responsible Care Association.

I hope you don't mind unsolicited info to provide a backdrop... I thought this was an interesting 2015 op-ed piece from Brookings https://www.brookings.edu/opinions/environmental-issues-facing-taiwan/. Public outcry and politics definitely come into play. Recently Taiwan EPA was trying to revamp their hazards classifications list reflect better scientific understanding. My understanding media and grandstanding politician created public fervor that derailed the effort, even though it made more sense. Just my interpretation of what I heard from multiple sources...

To be balances, the concerns are not unfounded. Again, for backdrop: https://business-humanrights.org/en/workplace-exposure-to-toxic-chemicals-lawsuit-re-taiwan
Hope this helps, Nancy.
Looking forward to seeing you in Taiwan. Maybe we can try one of the Restaurant Week places in DC, when we both return to the US?
Take care!
Andy
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ED_002682_00170692-00003

From: Liu, Andrew H [ANDREW.H.LIU@chemours.com]

Sent: 9/20/2017 1:52:06 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: Greetings!

Sensitivity: Private Flag: Follow up

Hi Nancy,

Hope your week is going well!

Here is what I have heard. Sorry if there's redundant information you already know.

I assume SAHTECH has been the people contacting you? As you know, they are a semi-governmental organization (http://www.sahtech.org/content/en/sahtech/About.aspx). Taiwan Environmental Protection Administration (EPA) contract services from SAHTECH for technical support. Dr. Li is a key leader and the main outward-facing representative for the organization. SAHTECH participates heavily in international meetings to represent Chinese Taipei.

I understand that SAHTECH has submitted a revised agenda to Taiwan EPA for approval before sending to you.

The main government sponsor is the Taiwan EPA Toxic Chemical Substance Bureau who has responsibility to implement the Toxic Chemical and Substances Control Act (TCSCA), but the opening will likely be by someone on the ministerial level. This is an important timing for Taiwan EPA because their New Chemicals program has started recently and their existing chemicals program is drafted, but not finalized. They are no longer simply implementing their version of REACH, like Korea. They are focusing their resources on the draft list of the initial 122 substances. And they are building flexibility in the data generation/requirements.

I am told that they are very interested in US EPA experience under TSCA and LCSA, such as changes, progress, status, lessons, stakeholder input/expectations, challenges. I think they are also interested in past experiences, such as the Work Plan.

My understanding is that you'll be the keynote speaker, followed by representatives from EU, Korea and Vietnam. It seems the second day will include additional words from you, followed by a panel discussion with Q/A, and an industry section in the afternoon. There may be a change of location to the Taiwan EPA offices for discussion among the regulators after the public forum.

Industry participation will be mostly by multinational companies, AMCHAM, and Taiwan Responsible Care Association.

I hope you don't mind unsolicited info to provide a backdrop... I thought this was an interesting 2015 op-ed piece from Brookings https://www.brookings.edu/opinions/environmental-issues-facing-taiwan/. Public outcry and politics definitely come into play. Recently Taiwan EPA was trying to revamp their hazards classifications list reflect better scientific understanding. My understanding media and grandstanding politician created public fervor that derailed the effort, even though it made more sense. Just my interpretation of what I heard from multiple sources...

To be balances, the concerns are not unfounded. Again, for backdrop: https://business-humanrights.org/en/workplace-exposure-to-toxic-chemicals-lawsuit-re-taiwan

Hope this helps, Nancy.

Looking forward to seeing you in Taiwan. Maybe we can try one of the Restaurant Week places in DC, when we both return to the US?

Take care!

Andy

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov] **Sent:** Wednesday, September 20, 2017 9:39 AM **To:** Liu, Andrew H < ANDREW.H.LIU@chemours.com>

Subject: RE: Greetings! **Sensitivity:** Private

Hi Andy,

Japan will be right after Taiwan, I think my talk will be on the 13^{th} in Tokyo, likely I will arrive on the 12^{th} or maybe the 11^{th} ? I'll have to figure that out.

Thanks Andy, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Liu, Andrew H [mailto:ANDREW.H.LIU@chemours.com]

Sent: Friday, September 15, 2017 8:18 AM **To:** Beck, Nancy < <u>Beck.Nancy@epa.gov</u>>

Subject: RE: Greetings! **Sensitivity:** Private

Hi Nancy,

It sounds like you had a great summer! Hmmm... yum... I have to figure out a way to try restaurant week in DC or New York... another day, when there's more time.

Pretty quiet summer, after March-April travels. I have not taken any vacations to speak of. Two weddings (a nephew over July 4 weekend and a niece over Easter weekend... not sure what's with the holiday weekends) and a family reunion in NH in July. Very nice to see everyone and celebrate, but no great eats I am looking forward to vacations in Oct-Dec: 4 days in Bay area to see my sister and have lunch at Chez Panisse (which I like a lot) and tour a couple of vineyards; Newport RI for a week of low key R&R after 4 weeks in Asia and should be able to find some good eats; Christmas in Hawaii (Dec 14-27) when I get to see my daughters. I have not found really exceptional eats on the big island, but love the fresh rambutan, lychee, Kona coffee, macadamia nuts, and shortbread (https://www.bigislandcandies.com/) that I really like.

As for Taiwan, I know some of the people who will attend, but will get back to you when I have better and more complete information.

I love visiting Japan! When will you be there? It sounds like a great opportunity to work with MOE! I have mostly dealt with METI and NITE, who participated in the OECD Clearing House on New Chemicals (http://www.oecd.org/chemicalsafety/risk-assessment/proceduresfornotificationofnewchemicals.htm). Really good

group, and I have the utmost respect for Greg Schweer. I think the work on correlation between available data and Polymer Exemption (or Polymer of Low Concern, PLC in some other countries) criteria is really cool (https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf)! My understanding is that this work contributed to Japan's decision to introduce a PLC option for their notification scheme.

OK... I have drunk the cool-aid. I really think these collaborative efforts with stakeholder input are good for society because governments can be more efficient and effective with available resources.

It's too bad that OECD did not choose to continue to sponsor this group. I can understand the rationale from the perspective of all the EU countries, for whom there are no longer "new chemicals". However, for the US, Canada, Australia, Japan, and the rest of the world, this is still relevant. I admire Greg's efforts to continue the effort independently. I think he said that Canada and Australia are interested and actively engaging. I am not sure if Japan is. I look forward to the new structure, but know it's a VERY busy time for OPPT CCD.

Take care! I'll send more info about Taiwan attendees, setting, etc.

Andy

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Thursday, September 14, 2017 6:27 PM

To: Liu, Andrew H < ANDREW.H.LIU@chemours.com >

Subject: RE: Greetings! **Sensitivity:** Private

Hi Andy,

Summer was good... Crop tours were fascinating Nonresponsive Discussion of Personal Matters / Ex. 6

Nonresponsive Discussion of Personal Matters / Ex. 6

Yes, I'm going to Taiwan—any insights you have on the meeting and attendees would be welcomed to help me understand the audience and what type of remarks would be useful.

I'm tacking onto it a trip to Japan as well to meeting with their Ministry of Environment. I'm very excited!! Looking forward to seeing you there.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Liu, Andrew H [mailto:ANDREW.H.LIU@chemours.com]

Sent: Wednesday, September 13, 2017 9:33 PM

To: Beck, Nancy < Beck. Nancy@epa.gov>

Subject: Greetings! **Sensitivity:** Private

Hi Nancy,

How was your summer? How was restaurant week and California?

Hope the crazy busy has calmed down a bit. Our "transformation" is still going strong.

I bought my tickets – I plan to spend Nov 2-6 in Japan to see my daughter and my Japanese colleagues. Then fly to Taiwan on the 7th to attend the regulatory forum, returning to the US on Nov 11. Mmm... soup dumplings, broth noodles, shaved ice...

Are you still planning to go?

Take care!

Andy

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From: m.lafore@dowcorning.com [m.lafore@dowcorning.com]

Sent: 9/15/2017 7:44:19 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Meeting Forward Notification: FW: Meeting w/Dow on PMN

Your meeting was forwarded

LAFORE, MICHAEL R. (MRLAFORE) has forwarded your meeting request to additional people.

Meeting

FW: Meeting w/Dow on PMN

Meeting Time

Friday, September 22, 2017 2:00 PM - Friday, September 22, 2017 3:00 PM

Recipients

GOLDBERG, CORTNEY E. (CEGOLDBE)

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

From: MicrosoftExchange329e71ec88ae4615bbc36ab6ce41109e@smtp.dowcornusa.com

[Microsoft Exchange 329e 71ec 88ae 4615bbc 36ab 6ce 41109e @smtp.dow cornus a.com]

on behalf of m.lafore@dowcorning.com [m.lafore@dowcorning.com]

Sent: 9/15/2017 7:44:22 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Meeting Forward Notification: Meeting w/Dow on PMN

Your meeting was forwarded

LAFORE, MICHAEL R. (MRLAFORE) has forwarded your meeting request to additional recipients.

Meeting

Meeting w/Dow on PMN

Meeting Time

Friday, 22 September 2017 14:00-15:00.

Recipients

GOLDBERG, CORTNEY E. (CEGOLDBE)

All times listed are in the following time zone: (GMT-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server 2007

Message

From: Liu, Andrew H [ANDREW.H.LIU@chemours.com]

Sent: 9/14/2017 1:32:47 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Greetings!

Sensitivity: Private

Hi Nancy,

How was your summer? How was restaurant week and California?

Hope the crazy busy has calmed down a bit. Our "transformation" is still going strong.

I bought my tickets – I plan to spend Nov 2-6 in Japan to see my daughter and my Japanese colleagues. Then fly to Taiwan on the 7th to attend the regulatory forum, returning to the US on Nov 11. Mmm... soup dumplings, broth noodles, shaved ice...

Are you still planning to go?

Take care!

Andy

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Message

From: White, Kimberly [Kimberly_White@americanchemistry.com]

Sent: 8/16/2017 8:38:21 PM

To: Goldstein, Bernard D [bdgold@pitt.edu]; Terry F. Yosie [tyosie@wec.org]; Beck, Nancy [Beck.Nancy@epa.gov]; Joe

Arvai [jlarvai@umich.edu]; rdenison@edf.org

Subject: RE: SRA 2017 Annual Meeting Roundtable Acceptance

Thanks for the update Bernie and looking forward to the session discussion.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
O: (202) 249-6707 C: (202) 341-7602

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]

Sent: Wednesday, August 16, 2017 8:13 AM

www.americanchemistry.com

To: Terry F. Yosie; White, Kimberly; Beck, Nancy; Joe Arvai; Richard Denison

Subject: FW: SRA 2017 Annual Meeting Roundtable Acceptance

Congratulations to us all. We are on the schedule for Tuesday afternoon, 12/12, from 1:30-3pm.

Just as a reminder:. The final order of presentations is open – it will be ten minutes each except for Terry who is our MC. Should leave 40 min for discussion. Again, the focus should be on the optimal principles and how best to achieve them rather than a critique of specific legislation. Our abstract is below

Recent activities by both Congress and by EPA Administrator Pruitt provide an opportunity to evaluate approaches for organizing risk-related scientific advisory processes for regulatory agencies. The EPA Science Advisory Board Reform Act has been passed by the US House of Representatives and is awaiting action in the US Senate, which may or may or may not be forthcoming. These have generated media interest and controversy and some have characterized these actions as unnecessarily politicizing science and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes. Others have pointed out that there is a need to broaden scientific representation in diverse fields, and to improve procedures for balancing perspectives and perceived biases on EPA scientific advisory panels. The Roundtable participants will be asked to focus on the underlying principles that should guide the science advisory processes for the optimal provision of scientific advice on risk-related issues to a regulatory agency.

Hope you are all having a good summer

Bernie

Subject: SRA 2017 Annual Meeting Roundtable Acceptance

What is the Optimal Approach to Organizing Governmental Risk-Related Science Advisory Processes

has been accepted for the 2017 Meeting in Arlington, VA on

10-14 December as a

Roundtable Session

on Tuesday, December 12, from 1:30 PM to 3:00 PM. The online program will be available by August 15. You will be able to view it by going to http://sra.org/events/sra-2017-annual-meeting

Please note that all persons attending the Annual Meeting (or any part thereof) are **REQUIRED** to pay the appropriate registration fee as indicated on the registration form. Most importantly, **ALL PRESENTERS IN YOUR ROUNTABLE SESSION MUST REGISTER FOR THE MEETING.** (Registration will open at the end of August at www.SRA.org.) If for any reason you need to cancel your presentation, as a courtesy to the Society and the other meeting participants, please contact your session chair, the Annual Meeting Committee chair (Terje Aven, terje.aven@uis.no), AND Jennifer Rosenberg of the SRA Secretariat (jrosenberg@burkinc.com) as soon as possible.

Please upload all Powerpoint presentations for your session by December 4 at http://burkinc.net/sraAM/index.php3. Instructions for the upload of your presentation will be posted at www.sra.org after 30 September. It is very important that you follow these instructions and upload before the meeting so the session will run smoothly.

Please go to www.sra.org to view the preliminary program and information for registering for the meeting (which will be posted soon). A room block has been set aside at the Crystal Gateway Marriott. Reservations can be made at the special SRA rate by using this link - https://aws.passkey.com/event/49022912/owner/1487/home

Thank you for your participation. We look forward to seeing you in Arlington in December.

Terje Aven

SRA President-Elect and Annual Meeting Chair

Jennifer Rosenberg

Director, Meetings and Events

Jennifer Rosenberg, CMP Director, Meetings and Events 1313 Dolley Madison Blvd. Suite 402 McLean VA 22101 703-790-1745 x214 Fax: 703-790-2672 irosenberg@burkinc.com

Message

From: Marty, Sue (S) [MSMarty@dow.com]

Sent: 8/17/2017 12:10:52 AM

To: Scarano, Louis [Scarano.Louis@epa.gov]; Deziel, Dennis (DR) [DRDeziel@dow.com]; Beck, Nancy

[Beck.Nancy@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Cleland-Hamnett, Wendy [Cleland-

Hamnett.Wendy@epa.gov]

CC: Witt, Mike (M) [MEWitt@dow.com]; Boverhof, Darrell (R) [RBoverhof@dow.com]; DiMuro, Johnathan (J)

[JDiMuro@dow.com]; LaFore, Mike (M) [m.lafore@dowcorning.com]

Subject: Thank you

Attachments: Marty Dow Predictive Toxicology and LCSA.pdf

Hi Dr. Scarano,

Thank you for meeting with me today. I really appreciate your time and I enjoyed our conversation. I think that we share similar views on how alternative approaches could be used in the TSCA program, providing that we can establish sufficient confidence to meet the Agency's needs. As we discussed, I will talk with my PMN team to see if they will have a case study ready for the November 2nd meeting. Also, I am attaching a copy of my slides from today in pdf format. If you would like the PowerPoint version, I can send these as well.

I look forward to talking with you further about how alternative approaches can be used in the TSCA program and how Dow can assist with this goal.

Good luck with the double move next week. I hope it goes well.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: mmarty@dow.com

From: Marty, Sue (S)

Sent: Friday, August 11, 2017 2:03 PM

To: 'Scarano, Louis'; Deziel, Dennis (DR); 'Beck, Nancy'; 'Morris, Jeff'; 'Cleland-Hamnett, Wendy'

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: Marty Visit next Wednesday

Hi Dr. Scarano,

I know that you will be out of the office on Monday and Tuesday next week, so, just to confirm, I will plan to arrive at the EPA (address below) shortly before our meeting next week on Wednesday, August 16, at 3 PM. I view this as an opportunity to give a brief overview of Dow's predictive tox program and then discuss possible ways that we can collaborate to evaluate the potential utility of these approaches. If you need any information from me in advance (e.g., a one pager, copies of slides, etc.), please let me know. I look forward to meeting you next week.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director Toxicology & Environmental Research and Consulting The Dow Chemical Company 1803 Building Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: <u>mmarty@dow.com</u>

From: Marty, Sue (S)

Sent: Friday, August 04, 2017 9:02 AM

To: 'Scarano, Louis'; Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dr. Scarano,

Thank you for getting back to me with a positive response. Lagree – Let's sort out the details next week. Llook forward to meeting you.

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: mmarty@dow.com

From: Scarano, Louis [mailto:Scarano.Louis@epa.gov]

Sent: Friday, August 04, 2017 8:23 AM

To: Marty, Sue (S); Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dr. Marty:

Sorry it will not work for Dennis. Looking forward to meeting and talking with you Dr. Marty.

I will be out of the office on Monday and Tuesday of that week (8/14 and 8/15), but we can firm up any details late next week.

Regards,

Louis (Gino) Scarano, PhD Senior Science Advisor (Detail)

US EPA

Office of Chemical Safety and Pollution Prevention (OCSPP)

Office of Pollution Prevention and Toxics (OPPT)

Risk Assessment Division (RAD)

1200 Pennsylvania Ave, NW (Mail Code 7403M)

Washington, DC 20460 Desk Phone: 202-564-2851 Mobile: 202-340-5726 Fax: 202-564-7450

Deliveries: Room 6208A, 1201 Constitution Ave., NW, Washington, DC 20460

From: Marty, Sue (S) [mailto:MSMarty@dow.com]

Sent: Thursday, August 03, 2017 3:50 PM

To: Scarano, Louis <<u>Scarano.Louis@epa.gov</u>>; Deziel, Dennis (DR) <<u>DRDeziel@dow.com</u>>; Beck, Nancy <Beck.Nancy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Cleland-Hamnett, Wendy <Cleland-

Hamnett.Wendy@epa.gov>

Cc: Witt, Mike (M) < MEWitt@dow.com >; Boverhof, Darrell (R) < RBoverhof@dow.com >; DiMuro, Johnathan (J)

<<u>JDiMuro@dow.com</u>>; LaFore, Mike (M) <<u>m.lafore@dowcorning.com</u>>

Subject: RE: Thank you & Follow-up

Dr. Scarano,

Unfortunately, Dennis Deziel is not available to meet on August 16th; however, I will be in Washington DC and would greatly appreciate an opportunity to meet with you. I am available on Wednesday (Aug. 16) from 3-4 PM. As Dennis mentioned, I would like to discuss the predictive toxicology program at Dow and some potential areas for collaboration. Please let me know if this time is still suitable for you. Thank you for considering my request.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: mmarty@dow.com

From: Scarano, Louis [mailto:Scarano.Louis@epa.gov]

Sent: Thursday, August 03, 2017 8:06 AM

To: Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Marty, Sue (S); Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dennis:

Thanks for the note and the visit.

I will be here on Wednesday, August 16th and would be happy to meet with you and Dr. Marty. As of now, the best times for me would be either 11-12 or 3-4. If that doesn't work for you, let me know and I might be able to re-arrange things (the only meeting I cannot change is my 2-3 pm).

Regards,

Louis (Gino) Scarano, PhD Senior Science Advisor (Detail) US EPA

Office of Chemical Safety and Pollution Prevention (OCSPP)

Office of Pollution Prevention and Toxics (OPPT)

Risk Assessment Division (RAD)

1200 Pennsylvania Ave, NW (Mail Code 7403M)

Washington, DC 20460
Desk Phone: 202-564-2851
Mobile: 202-340-5726
Fax: 202-564-7450

Deliveries: Room 6208A, 1201 Constitution Ave., NW, Washington, DC 20460

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Wednesday, August 02, 2017 10:18 AM

To: Scarano, Louis <<u>Scarano.Louis@epa.gov</u>>; Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>; Morris, Jeff <<u>Morris.Jeff@epa.gov</u>>;

Cleland-Hamnett, Wendy < Cleland-Hamnett. Wendy@epa.gov >

Cc: MSMarty@dow.com; Witt, Mike (M) < MEWitt@dow.com >; Boverhof, Darrell (R) < RBoverhof@dow.com >; DiMuro,

Johnathan (J) < JDiMuro@dow.com>; LaFore, Mike (M) < m.lafore@dowcorning.com>

Subject: Thank you & Follow-up

Nancy, Wendy, Jeff, Gino:

Thank you again for your time yesterday – extremely helpful for us. Let us know if you need anything from us on the 5(f) issue or on NAFTA follow-up. On NAFTA, we could help organize a meeting to discuss the pros of a chemical sector chapter if you are interested.

Gino, Dr. Sue Marty will be in DC on **August 16**th in DC. Is there any chance we could link up with you to discuss the specifics of our alternatives program and potential areas of collaboration?

Thank you again, Dennis

Dennis Deziel

Government Affairs

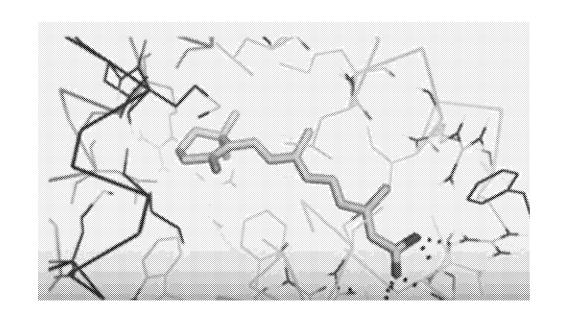
500 North Capitol St NW, Suite 200, Washington, D.C. 20001 +1-202-429-3420 | +1-202-579-7593 | <u>Drdeziel@dow.com</u>

Introducing @dowpolicy - Let's talk together to solve together



Dow's Predictive Toxicology Program and the LCSA

Sue Marty, PhD, DABT TERC Science Director August 16, 2017









Agenda

- An Introduction to TERC
 - Why does Dow need a Predictive Toxicology Program?
- Dow's Predictive Tox Program
 - Five Science Pillars
- TSCA/LCSA
 - An Integrated Approach
 - Opportunities to Partner?







TERC- Toxicology and Environmental Research and Consulting

A Toxicology testing and consulting expertise center within Dow

An industry leader in applying the best science and technology to:

Support sustainable product development (guide decision making)

Seneffe, Belgium

Horgen,

Switzerland

- Support product registrations to speed time to market
- Address complex product safety questions

Midland, MI













Protecting human health and the environment



- ~200 people globally
 - Full-service Toxicology Lab in Midland Michigan
 - **Expert Internal Toxicology Consultants- Globally**
- > 70 advanced degrees in Toxicology or related disciplines (Ph.D, M.Sc., DVM, DABT)
- World Class Expertise in Traditional and 21st Century Toxicology testing approaches





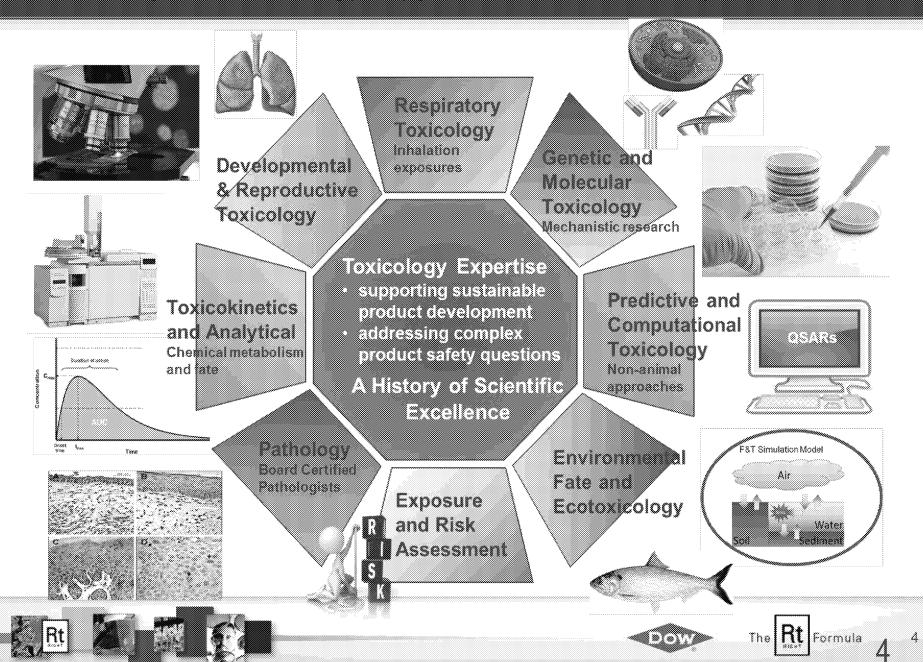
Shanghai, Beijing

and Taipei

Mumbai. India



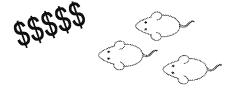
TERC: Complete Toxicology Support for Product Safety Assessment

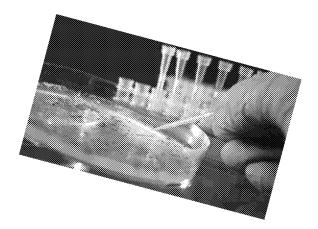


Why Does Dow Need a Predictive Tox Program?

- PT applications in modern chemical product safety assessment
 - Design and select more sustainable products
 - Tailor regulatory testing based on alerts
 - Save time, money and animals







- Increase confidence in chemical technology (2025)
 - More attention to front end = less effort defending commercialized molecules
- Integrated testing strategy
 - Predictive approaches + conventional animal testing





Dow's Predictive Toxicology Program

Cheminformatics

Bioprofiling

Toxicokinetics

Environ Chem/Tox

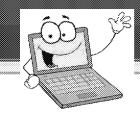
Exposure

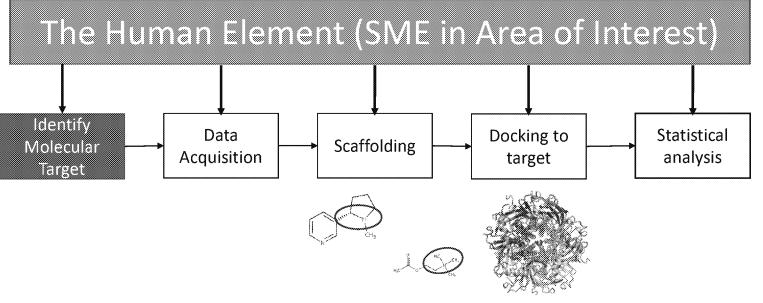






Cheminformatics: Identifying Cholinergics





	Nicotinic ACh	Muscarinic ACh	<u>Acetylcholinest</u>
	<u>Receptor</u>	Receptor	<u>erase</u>
Sensitivity	96.44%	99.33%	98.91%
Specificity	82.35%	50.49%	23.94%
Predictive Negative Value	98.12%	98.93%	96.57%
Accuracy	86.68%	72.49%	56.78%







TERC Cheminformatics: Mechanisms of Acute Toxicity

Reactivity

- Acids/bases protein denaturation
- Non-specific protein-binding via reactivity
- Metabolism to reactive protein-binder
- Alkylation
- Radiation poisoning DNA/tissue destruction
- PhysChem properties subject to precipitation

Non-specific lipid membrane disruption

- Chelation
- Mitotic spindle poison by binding tubulin
- Energy
 - Mitochondria inhibition
 - Phosphorylation of glucose inhibition
 - Hexokinase (glycolysis) inhibition
 - Transketolase (glycolysis) inhibition
 - Inhibit pyruvate dehydrogenase (glycolysis)
 - Bcr-Abltyrosine kinase inhibition
 - Inhibit aconitase (TCA cycle)

Vitamin interference

- Vit B6: Pyridoxine phosphokinase
- Ubiquinone analogs
- Folate analogs

Protein synthesis inhibit

Nucleotide synthesis inhibit

- GMP synthetase inhibit purine biosyn
- G6PD inhibition
- IMP dehydrogenase inhibit purine biosyn
- Adenylsuccinate synthetase inhibit purine biosyn
 - Adenylsuccinase inhibit purine biosyn

Blood

- Anticoagulation
- Heme biosynthesis inhibit

Vasoactive/blood pressure

Histamine activation – inhibit ligand-gated Cl⁻ channel

G-Protein coupled receptors

- 5-Hydroxytryptamine) receptor
- α-β Adrenergic receptor agonist
- GABA receptor
- Dopamine receptor
- Adenosine receptor
- CNS μ-, d-, K-opioid receptors

Cys-loop ligand gaited ion channels

- Nicotinic acetylcholine receptor
- GABA receptor
- Glycine receptor
- 5-HT₃ (5-Hydroxytryptamine) receptor

Neuro/lon Channel Signaling

- Acetylcholinesterase inhibit
- Voltage-gaited channels
- Sodium/potassium ATPase
- Block synthesis of neurotransmitter glutamate
- Norepinephrine reuptake inhibitor
- NMDA receptors
- Ether-a-go-go (ERG) voltage-gated K* channel

Aryl hydrocarbon receptor

- Beta2-macroglobulin binding kidney
- Nuclear receptors; Transcription factors





Bioprofiling: Current in vitro Capabilities

Dermal corrosion & irritation

- Corrositex
- EpiDerm corrosion
- EpiDerm irritation

Ocular corrosion & irritation

- BCOP
- NRR
- EpiOcular

Skin sensitization

- KeratinoSens
- DPRA
- SENS-IS (2017)

Phototoxicity

■ 3T3 NRU

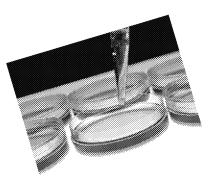
Respiratory irritation

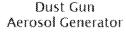
- EpiAirway
- MucilAirway

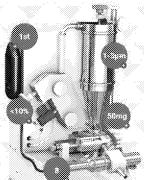
Cancer MOA

- NR expression in hepatocytes
- Genomics









Acute oral/dermal/inhalation

- No good in vitro assays
- Basal cytotoxicity
- Calculation method for formulations

Endocrine

- ER/AR binding
- ER/AR transactivation
- Aromatase
- Steroidogenesis

DART

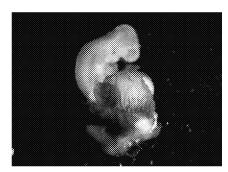
- WEC
- Zebrafish embryo
- Genomics

Genetic Toxicity

- RLCAT
- In vitro MNT
- Hgprt

Oxidative stress

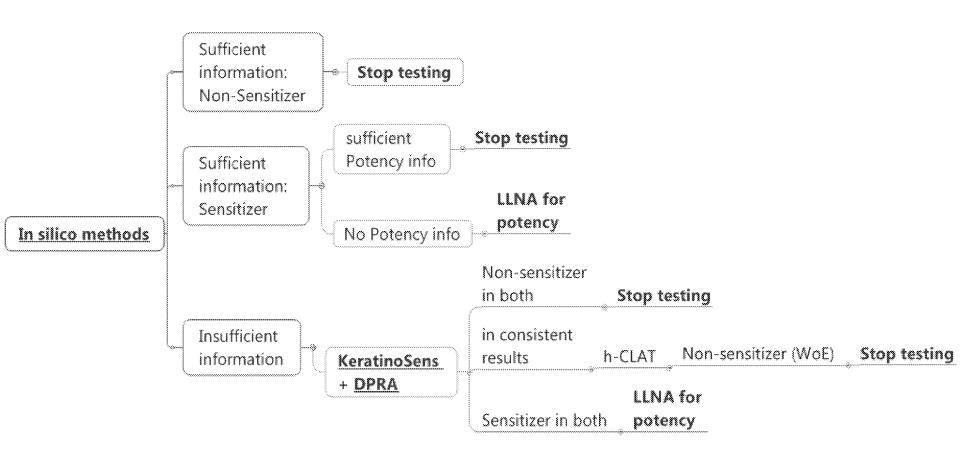
ROS, Mt activity, cytotoxicity







Integrated Approaches to Testing and Assessment: Sensitization



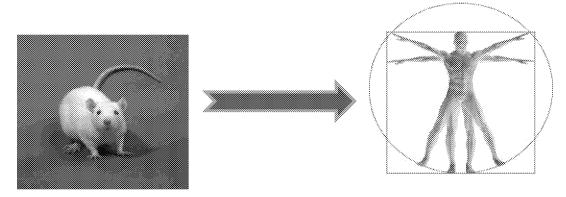




In Silico Toxicokinetics: GastroPlus Modeling

GastroPlus to predict:

- Systemic exposure/Bioavailability
- Absorption rates, Metabolic clearance, Plasma protein binding and Tissue distribution
- Parent compound and metabolite(s)
- In vitro-to-in vivo extrapolations (IVIVE)
- Support for multiple exposure routes (oral, inhalation, dermal)
- Supports various species (human, rat) and life stages

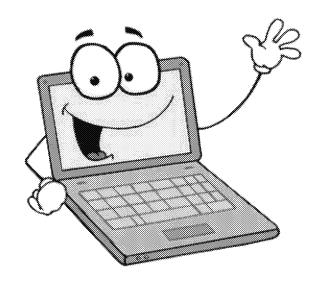




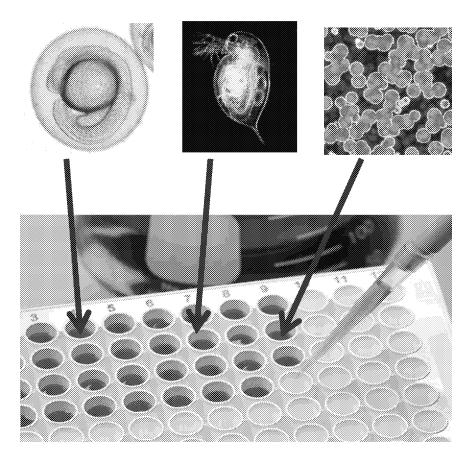


Environmental Chemistry and Toxicology

Predictions of the persistence and environmental fate of chemicals in the environment as well as their effects on taxa in the environment



(e.g., Biodegradation, persistence, fate, bioconcentration factor, acute/aquatic toxicity)



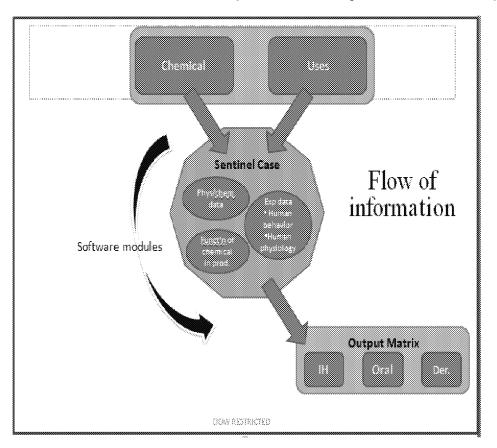






Exposure: HEAT Model

Using *in silico* models as a high-throughput approach to predict human exposures to environmental chemicals, particularly consumer products.









Application: HEAT Case Study with Cleaning Solvent

35 Aggregate exposure to one chemical Solvent use in household cleaners; 3 exposure routes Ten most frequently used groups of cleaners One from each group with average percentage of chemical in formulation "Spring cleaning" scenario 15 10 5 Glass cleaner Floor cleaning Furniture Bathroom Liquid cleaner Abrasive Detergent Carpet Spray cleaner Aggregate REACH DNEL dishwashing liquid leather spray cleaning powder liquid deaning

liquid



liquid



liquid



TSCA/LCSA APPLICATIONS







Current EPA PMN Assessment Process

With insufficient tox data, the New Chemicals Program may:

- Run the 'Sustainable Futures' tools
- Use read-across, possibly based on CBI (PMN) information
- Issue consent orders and SNURs

Health or environmental hazard concerns

- Often leads directly to in vivo testing
- Extensive hazard characterization limited consideration of exposure





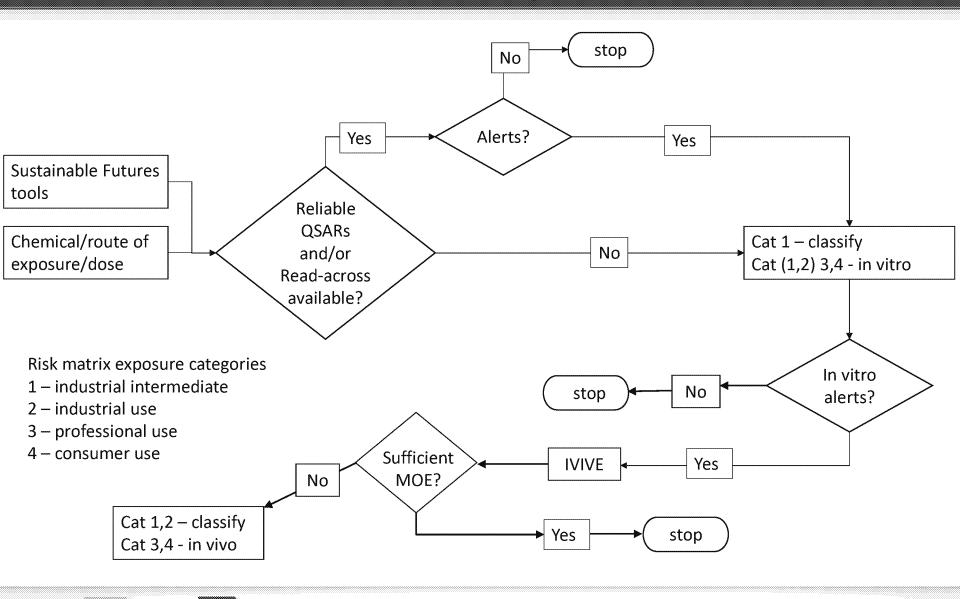
A Proposed Approach to PMNs

- Exposure-driven and Risk-based for reasonably foreseen uses
- Greater use of non-animal methods for hazard screening
 - EPA guidance: Incorporate alternative approaches in risk assessment
- Integrated approach to evaluate 'Sustainable Futures' endpoints
 - Take into account existing data from other jurisdictions (ECHA, Canada, other programs)
 - Use in silico methods (i.e., read-across, categories, QSAR)
 - Use in vitro approaches
 - Margins of safety determine need for animal testing





Hazard Identification with Exposure Consideration









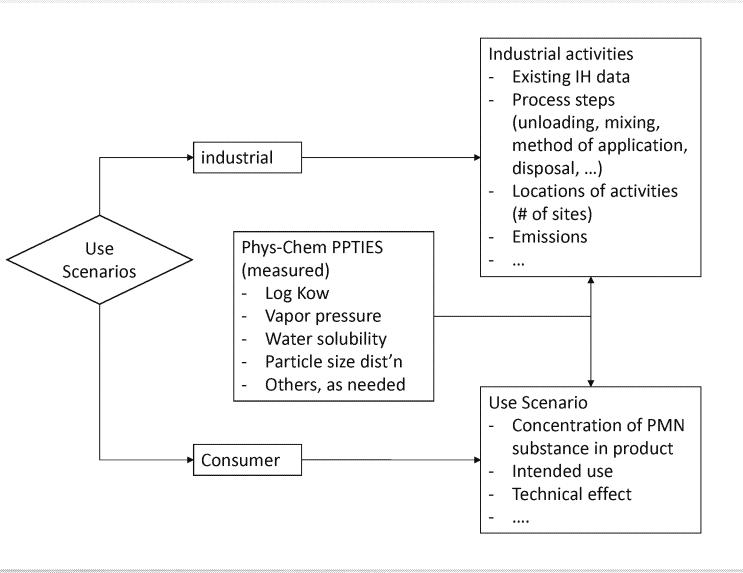
Dow Proposed Process

- Incorporate IATAs for Sustainable Futures endpoints
 - Mutagenicity
 - Sensitization
 - Irritation
 - Aquatic toxicity
 - Biodegradation
 - Bioaccumulation
 - Others as they become available





Exposure Assessment



Exposure Assessment

- Who
- What route
- How much
- How often
- For how long
- Environmental compartment
- Trophic level
- Frequency of emission







Outcome of Dow Proposal

Evaluation of potential RISK for intended conditions of use

- Determine if additional refinement is needed (animal testing, measure exposures, etc...)
- Risk informs decisions, i.e., whether to support certain applications, require engineering controls or PPE, C&L, etc...





Next Steps:

- Desire to partner with EPA
 - With the program office to improve registration process
 - With ORD/research groups to incorporate alternative approaches for regulatory use
- Dow to submit a case study for PMN review
- Visit TERC Laboratory
 - Coincide with ACC LRI discussions
- EPA development of a strategic plan for incorporating alternative approaches











Message

From: Scarano, Louis [Scarano.Louis@epa.gov]

Sent: 8/17/2017 11:57:27 AM

To: MSMarty@dow.com; Deziel, Dennis (DR) [DRDeziel@dow.com]; Beck, Nancy [Beck.Nancy@epa.gov]; Morris, Jeff

[Morris.Jeff@epa.gov]; Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]

CC: Witt, Mike (M) [MEWitt@dow.com]; Boverhof, Darrell (R) [RBoverhof@dow.com]; DiMuro, Johnathan (J)

[JDiMuro@dow.com]; LaFore, Mike (M) [m.lafore@dowcorning.com]

Subject: RE: Thank you

Sue:

Thanks for the slides and coming over to the office.

Looking forward to collaborations...and please call me Gino!

Regards,

Louis (Gino) Scarano, PhD Senior Science Advisor (Detail)

US EPA

Office of Chemical Safety and Pollution Prevention (OCSPP)

Office of Pollution Prevention and Toxics (OPPT)

Risk Assessment Division (RAD)

1200 Pennsylvania Ave, NW (Mail Code 7403M)

Washington, DC 20460 Desk Phone: 202-564-2851 Mobile: 202-340-5726 Fax: 202-564-7450

Deliveries: Room 6208A, 1201 Constitution Ave., NW, Washington, DC 20460

From: Marty, Sue (S) [mailto:MSMarty@dow.com]

Sent: Wednesday, August 16, 2017 8:11 PM

To: Scarano, Louis <Scarano.Louis@epa.gov>; Deziel, Dennis (DR) <DRDeziel@dow.com>; Beck, Nancy <Beck.Nancy@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Cleland-Hamnett, Wendy <Cleland-

Hamnett.Wendy@epa.gov>

Cc: Witt, Mike (M) <MEWitt@dow.com>; Boverhof, Darrell (R) <RBoverhof@dow.com>; DiMuro, Johnathan (J)

<JDiMuro@dow.com>; LaFore, Mike (M) <m.lafore@dowcorning.com>

Subject: Thank you

Hi Dr. Scarano,

Thank you for meeting with me today. I really appreciate your time and I enjoyed our conversation. I think that we share similar views on how alternative approaches could be used in the TSCA program, providing that we can establish sufficient confidence to meet the Agency's needs. As we discussed, I will talk with my PMN team to see if they will have a case study ready for the November 2nd meeting. Also, I am attaching a copy of my slides from today in pdf format. If you would like the PowerPoint version, I can send these as well.

I look forward to talking with you further about how alternative approaches can be used in the TSCA program and how Dow can assist with this goal.

Good luck with the double move next week. I hope it goes well.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: mmarty@dow.com

From: Marty, Sue (S)

Sent: Friday, August 11, 2017 2:03 PM

To: 'Scarano, Louis'; Deziel, Dennis (DR); 'Beck, Nancy'; 'Morris, Jeff'; 'Cleland-Hamnett, Wendy'

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: Marty Visit next Wednesday

Hi Dr. Scarano,

I know that you will be out of the office on Monday and Tuesday next week, so, just to confirm, I will plan to arrive at the EPA (address below) shortly before our meeting next week on Wednesday, August 16, at 3 PM. I view this as an opportunity to give a brief overview of Dow's predictive tox program and then discuss possible ways that we can collaborate to evaluate the potential utility of these approaches. If you need any information from me in advance (e.g., a one pager, copies of slides, etc.), please let me know. I look forward to meeting you next week.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674
Tolophone: (989) 636 6653

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: <u>mmarty@dow.com</u>

From: Marty, Sue (S)

Sent: Friday, August 04, 2017 9:02 AM

To: 'Scarano, Louis'; Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dr. Scarano,

Thank you for getting back to me with a positive response. Lagree – Let's sort out the details next week. Llook forward to meeting you.

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: mmarty@dow.com

From: Scarano, Louis [mailto:Scarano.Louis@epa.gov]

Sent: Friday, August 04, 2017 8:23 AM

To: Marty, Sue (S); Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dr. Marty:

Sorry it will not work for Dennis. Looking forward to meeting and talking with you Dr. Marty.

I will be out of the office on Monday and Tuesday of that week (8/14 and 8/15), but we can firm up any details late next week.

Regards,

Louis (Gino) Scarano, PhD Senior Science Advisor (Detail)

US EPA

Office of Chemical Safety and Pollution Prevention (OCSPP)

Office of Pollution Prevention and Toxics (OPPT)

Risk Assessment Division (RAD)

1200 Pennsylvania Ave, NW (Mail Code 7403M)

Washington, DC 20460 Desk Phone: 202-564-2851 Mobile: 202-340-5726 Fax: 202-564-7450

Deliveries: Room 6208A, 1201 Constitution Ave., NW, Washington, DC 20460

From: Marty, Sue (S) [mailto:MSMarty@dow.com]

Sent: Thursday, August 03, 2017 3:50 PM

To: Scarano, Louis <<u>Scarano.Louis@epa.gov</u>>; Deziel, Dennis (DR) <<u>DRDeziel@dow.com</u>>; Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>; Morris, Jeff <<u>Morris.Jeff@epa.gov</u>>; Cleland-Hamnett, Wendy <<u>Cleland-</u>

Hamnett.Wendy@epa.gov>

Cc: Witt, Mike (M) <MEWitt@dow.com>; Boverhof, Darrell (R) <RBoverhof@dow.com>; DiMuro, Johnathan (J)

<JDiMuro@dow.com>; LaFore, Mike (M) <m.lafore@dowcorning.com>

Subject: RE: Thank you & Follow-up

Dr. Scarano,

Unfortunately, Dennis Deziel is not available to meet on August 16th; however, I will be in Washington DC and would greatly appreciate an opportunity to meet with you. I am available on Wednesday (Aug. 16) from 3-4 PM. As Dennis mentioned, I would like to discuss the predictive toxicology program at Dow and some potential areas for collaboration. Please let me know if this time is still suitable for you. Thank you for considering my request.

Kindest Regards,

Sue

Sue Marty, Ph.D., D.A.B.T.

TERC Science Director
Toxicology & Environmental Research and Consulting
The Dow Chemical Company
1803 Building
Midland, MI 48674

Telephone: (989) 636-6653 FAX: (989) 638-9863 E-mail: <u>mmarty@dow.com</u>

From: Scarano, Louis [mailto:Scarano.Louis@epa.gov]

Sent: Thursday, August 03, 2017 8:06 AM

To: Deziel, Dennis (DR); Beck, Nancy; Morris, Jeff; Cleland-Hamnett, Wendy

Cc: Marty, Sue (S); Witt, Mike (M); Boverhof, Darrell (R); DiMuro, Johnathan (J); LaFore, Mike (M)

Subject: RE: Thank you & Follow-up

Dennis:

Thanks for the note and the visit.

I will be here on Wednesday, August 16th and would be happy to meet with you and Dr. Marty. As of now, the best times for me would be either 11-12 or 3-4. If that doesn't work for you, let me know and I might be able to re-arrange things (the only meeting I cannot change is my 2-3 pm).

Regards,

Louis (Gino) Scarano, PhD
Senior Science Advisor (Detail)
US EPA
Office of Chemical Safety and Pollution Prevention (OCSPP)
Office of Pollution Prevention and Toxics (OPPT)
Risk Assessment Division (RAD)
1200 Pennsylvania Ave, NW (Mail Code 7403M)
Washington, DC 20460

Desk Phone: 202-564-2851 Mobile: 202-340-5726 Fax: 202-564-7450

ED_002682_00175839-00004

Deliveries: Room 6208A, 1201 Constitution Ave., NW, Washington, DC 20460

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Wednesday, August 02, 2017 10:18 AM

To: Scarano, Louis <<u>Scarano.Louis@epa.gov</u>>; Beck, Nancy <<u>Beck.Nancy@epa.gov</u>>; Morris, Jeff <<u>Morris.Jeff@epa.gov</u>>;

Cleland-Hamnett, Wendy < Cleland-Hamnett. Wendy@epa.gov >

Cc: MSMarty@dow.com; Witt, Mike (M) < MEWitt@dow.com >; Boverhof, Darrell (R) < RBoverhof@dow.com >; DiMuro,

Johnathan (J) <JDiMuro@dow.com>; LaFore, Mike (M) <m.lafore@dow.corning.com>

Subject: Thank you & Follow-up

Nancy, Wendy, Jeff, Gino:

Thank you again for your time yesterday – extremely helpful for us. Let us know if you need anything from us on the 5(f) issue or on NAFTA follow-up. On NAFTA, we could help organize a meeting to discuss the pros of a chemical sector chapter if you are interested.

Gino, Dr. Sue Marty will be in DC on August 16th in DC. Is there any chance we could link up with you to discuss the specifics of our alternatives program and potential areas of collaboration?

Thank you again, Dennis

Dennis Deziel

Government Affairs

500 North Capitol St NW, Suite 200, Washington, D.C. 20001 +1-202-429-3420 | +1-202-579-7593 | Drdeziel@dow.com

Introducing @dowpolicy - Let's talk together to solve together







WORLDWIDE PARTNER

Appointment

From: HOPPER, SARA ELIZABETH [Sara.E.Hopper@dupont.com]

Sent: 8/9/2017 3:01:41 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Declined: ESA/FIFRA Issue

Location: RM 3156 EPA East

Start: 8/18/2017 7:00:00 PM **End**: 8/18/2017 7:30:00 PM

Show Time As: Busy

Recurrence: (none)

From: HOPPER, SARA ELIZABETH [Sara.E.Hopper@dupont.com]

Sent: 8/9/2017 3:01:42 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: Read: [EXTERNAL] ESA/FIFRA Issue
Attachments: Read: [EXTERNAL] ESA/FIFRA Issue

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Delivery Report

From: HOPPER, SARA ELIZABETH [Sara.E.Hopper@dupont.com]

Sent: 8/9/2017 3:01:42 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]
Subject: Read: [EXTERNAL] ESA/FIFRA Issue

Your message

To: HOPPER, SARA ELIZABETH
Subject: [EXTERNAL] ESA/FIFRA Issue
Sent: 8/9/2017 12:40:29 AM

was read 8/9/2017 on 3:01:42 AM

Your message

To: HOPPER, SARA ELIZABETH Subject: [EXTERNAL] ESA/FIFRA Issue

Sent: Tuesday, August 8, 2017 8:40:29 PM (UTC-05:00) Eastern Time (US & Canada)

was read on Tuesday, August 8, 2017 11:01:42 PM (UTC-05:00) Eastern Time (US & Canada).

From: DEKLEVA, LYNN ANN [Lynn-Ann.Dekleva-1@dupont.com]

Sent: 8/7/2017 2:56:56 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Polymer Exemption Technical Contact Request

Nancy,

I am trying to find a contact at the agency to have a technical discussion on the definition of "degradation" for Polymer Exemptions. I tried submitting my question through the normal channels but ended up hitting a dead end. Can you provide a contact? Thanks for your help.

Regards, Lynn

Lynn Ann Dekleva, PhD Product Stewardship & Regulatory Senior Consultant DuPont Chestnut Run Plaza 702/2304F 974 Centre Road Wilmington, DE 19805 (302)999-2353 (302)593-1188 (Cell)

----Original Message----

From: DEKLEVA, LYNN ANN

Sent: Wednesday, July 12, 2017 1:28 PM To: Schutz, David <Schutz.David@epa.gov>

Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Ross, Adam <ross.adam@epa.gov>; Lee, Doyoung

<Lee.Doyoung@epa.gov>; Anapolle, Kent <Anapolle.Kent@epa.gov>

Subject: RE: Form submission from: Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

Reviewing New Chemicals under TSCA Contact Us form

Dave,

I have reviewed the regulation and responses to inquiries regarding degradation. The intent of the biodegradation exclusion for the polymer exemption was for polymers that undergo substantial degradation under normal conditions of use or disposal. In their discussion, the Agency acknowledged that essentially all polymers degrade or decompose to a limited degree over time and gave examples of polymers in landfills and stated that the exclusion was not intended to address such degradation. If the polymer is designed or reasonably anticipated to substantially degrade then they would be excluded from the polymer exemption. Substantial biodegradation in a waste treatment system (readily biodegrability test which simulates a waste water treatment plant) would render a polymer ineligible for the exemption. The question I have is: to assess the degradability of a polymer for potential polymer exemption, a reasonable assessment would be the Readily biodegradability test? Aerobic composting is not a reasonable assessment of the degradability potential of the materials for the polymer exemption since this method of disposal generally are restricted to yard, food and farm wastes with only a small amount of industrial wastes reported to be composted. The fate of the material in landfills will inform the cradle to grave assessment and potential fate of the material but should not be used to assess the material for polymer exemption.

Regards, Lynn

Lynn Ann Dekleva, PhD
Product Stewardship & Regulatory Senior Consultant DuPont Chestnut Run Plaza 702/2304F
974 Centre Road
Wilmington, DE 19805
(302)999-2353
(302)593-1188 (Cell)

----Original Message----

From: Schutz, David [mailto:Schutz.David@epa.gov]

Sent: Wednesday, July 12, 2017 12:02 PM

To: DEKLEVA, LYNN ANN <Lynn-Ann.Dekleva-1@dupont.com>

Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Ross, Adam <ross.adam@epa.gov>; Lee, Doyoung

<Lee.Doyoung@epa.gov>; Anapolle, Kent <Anapolle.Kent@epa.gov>

Subject: [EXTERNAL] RE: Form submission from: Reviewing New Chemicals under the Toxic Substances Control Act (TSCA) Reviewing New Chemicals under TSCA Contact Us form

Can you let me know a little more about your concerns? We have written some letter responses to inquiries about degradation, and I'd like to see of text from them can be helpful for you. Dave Schutz

----Original Message----

From: drupal_admin@epa.gov [mailto:drupal_admin@epa.gov]

Sent: Wednesday, July 12, 2017 11:36 AM
To: Schutz, David <Schutz.David@epa.gov>

Subject: Form submission from: Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)

Reviewing New Chemicals under TSCA Contact Us form

Submitted on 07/12/2017 11:35AM

Submitted values are:

Name: Lynn Dekleva

Email: Tynn-ann.dekleva-1@dupont.com

Comments:

I would like to have a technical discussion on the definition of degradation for the Polymer Exemption. The guidance document does outline that extensive degradation would make the material ineligible for the polymer exemption.

Can you please provide a contact within the agency with whom I can set up a meeting?

Thanks

Web Area: Reviewing New Chemicals under the Toxic Substances Control Act

(TSCA)

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From: Jain, Komal [Komal_Jain@americanchemistry.com]

Sent: 8/4/2017 6:34:47 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist). Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best, Komal

Komal K. Jain, J.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division komal_jain@americanchemistry.com 700 2nd Street, NE | Washington, DC | 20002

o: (202) 249-6212 m: (703) 608-5434

From: Jain, Komal [Komal_Jain@americanchemistry.com]

Sent: 8/7/2017 8:51:18 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: hiring?

Attachments: Craig W Hershberg_U.S. EPA_resume.docx

Flag: Flag for follow up

Thanks so much Nancy. See attached

A few quick highlights:

- Formerly worked for Toshiba America, Inc. and the U.S. EPA
- Experienced manager with specialized expertise meeting global compliance challenges, including product recycling, energy efficiency, restricted substance compliance, responsible sourcing and sustainability.
- Experienced manufacturing plant auditor.
- Experience working with trade associations, Congress, and government agencies on behalf of Toshiba and the U.S. EPA.

Best, Komal

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, August 4, 2017 2:53 PM

To: Jain, Komal < Komal_Jain@americanchemistry.com>

Subject: RE: hiring?

Ok. definitely send a CV. There is a hiring freeze (unless he wants to be a fellow ©

Nonresp

Nonresponsive Discussion of Personal Matters / Ex. 6

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]

Sent: Friday, August 4, 2017 2:45 PM **To:** Beck, Nancy Beck.Nancy@epa.gov

Subject: RE: hiring?

He would certainly consider it.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, August 4, 2017 2:38 PM

To: Jain, Komal < Komal _ Jain@americanchemistry.com>

Subject: RE: hiring?

Hev Komal

Nonresponsive Discussion of Personal Matters / Ex. 6

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]

Sent: Friday, August 4, 2017 2:35 PM
To: Beck, Nancy < Beck. Nancy @epa.gov >

Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist). Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best, Komal

Komal K. Jain, J.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division komal_jain@americanchemistry.com 700 2nd Street, NE | Washington, DC | 20002

o: (202) 249-6212 m: (703) 608-5434

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From: Melissa Hockstad [MHockstad@CleaningInstitute.org]

Sent: 8/1/2017 4:54:20 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Meeting with ACI

Nancy,

Thank you again for taking the time to meet with me today to discuss EPA's current priorities and areas of focus. I enjoyed meeting you and look forward to working with you and your team in the future.

Kind regards, Melissa

From: Melissa Hockstad

Sent: Monday, July 10, 2017 7:46 AM **To:** 'Beck, Nancy' <Beck.Nancy@epa.gov>

Cc: Marshall, Venus <Marshall.Venus@epa.gov>; Gena Tapscott-Cooper <GTapscott-Cooper@CleaningInstitute.org>

Subject: RE: Scheduling Brief Meeting with ACI

Thanks Nancy.

My colleague Gena will reach out to Venus so we can get something on the calendar for the week of July 31.

I hope you have a great week.

Kind regards, Melissa

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, July 7, 2017 7:13 PM

To: Melissa Hockstad < MHockstad@CleaningInstitute.org >

Cc: Marshall, Venus < <u>Marshall.Venus@epa.gov</u>> **Subject:** RE: Scheduling Brief Meeting with ACI

Melissa,

I would be happy to catch up. Things haven't quite slowed down yet, but I'm hoping they will soon.

Perhaps we can get something on the calendar now for the week of July 31st? If that works for you, please work with Venus to find a window that will stick on my calendar.

Regards, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Email / Ex. 6

beck.nancy@epa.gov

From: Melissa Hockstad [mailto:MHockstad@CleaningInstitute.org]

Sent: Thursday, July 6, 2017 9:19 AM

To: Beck, Nancy < Beck.Nancy@epa.gov > **Subject:** Scheduling Brief Meeting with ACI

Nancy,

I hope you are doing well. I wanted to know if you might have time to meet for a quick cup of coffee or brief introductory meeting this summer. I wanted to introduce myself to you as I joined ACI earlier this year.

I know your schedule is busy however please let me know if you might even have 15 minutes, and I'd be happy to stop by your office. I look forward to hearing from you. Thanks.

Kind regards, Melissa

Melissa Hockstad | President & CEO | American Cleaning Institute® 1331 L Street NW, Suite 650, Washington, DC 20005 | p: 202.662.2504 mhockstad@cleaninginstitute.org



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From: Liu, Andrew H [ANDREW.H.LIU@chemours.com]

Sent: 8/1/2017 1:44:02 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Aug 15, 16, or 17

Sensitivity: Private

Hi Nancy,

How have you been?

Nonresponsive Discussion of Personal Matters / Ex. 6

I checked with SAHTECH. The Nov 9 forum sounds interesting, so I think I will return to Taiwan after going to Japan.

Nonresponsive Discussion of Personal Matters / Ex. 6

In any case, take care!

Andy

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From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 8/1/2017 7:21:42 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]; Marshall, Venus [Marshall.Venus@epa.gov]

Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

We are here!

Get Outlook for Android

From: Deziel, Dennis (DR)

Sent: Wednesday, July 19, 2017 10:01:48 AM

To: Beck, Nancy; Marshall, Venus

Cc: Witt, Mike (M)

Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Venus,

We can be available on August 1 at either 11am or anytime 3:30pm or later. 30 minutes would be great. Thank you!

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Tuesday, July 18, 2017 5:44 PM

To: Deziel, Dennis (DR) <DRDeziel@dow.com> **Cc:** Marshall, Venus <Marshall.Venus@epa.gov>

Subject: RE: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Dennis-

I'm happy to meet with Mike Witt and can invite our leads for the development of our alternatives strategy. Please work with Venus to find a 30 minute window that will work.

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

beck.nancy@epa.gov

From: Deziel, Dennis (DR) [mailto:DRDeziel@dow.com]

Sent: Tuesday, July 18, 2017 1:18 PM **To:** Beck, Nancy Beck.Nancy@epa.gov>

Subject: Chemical Makers Urge EPA to Accept Non-Animal Safety Data

Nancy,

Dow is a leader in non-animal testing methods, including extensive, collaborative work with EPA's National Center for Computational Toxicology. We want to engage on this issue in as helpful way as possible. One of our leaders on this issue, Mike Witt, head of our toxicology center, will be in town August 1^{st} . Would you be available to meet when he is here to discuss this issue? Or we could meet with others as you recommend.

Thank you, Dennis

Dennis Deziel Government Affairs The Dow Chemical Company 500 North Capitol Street, NW Suite 200 Washington DC 20001 (202) 429-3420 (office) | (202) 579-7593 (cell)

E-Mail: DRDeziel@dow.com



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Bloomberg News

Chemical Makers Urge EPA to Accept Non-Animal Safety Data

By Pat Rizzuto

Chemical manufacturers want the EPA to be more receptive than they say the European Chemicals Agency has been in accepting chemical safety data derived from non-animal tests.

"We've had challenges in the EU getting many of these alternatives accepted. We hope the U.S. will be a more friendly place," Athena Keene, a senior toxicologist at Afton Chemical Corp., said at a recent science policy meeting.

Afton, a subsidiary of the NewMarket Corp., which makes fuel and lubricant additives, has registered chemicals under the EU's registration, evaluation, authorization and restriction of chemicals, or REACH, law. REACH encourages the use of non-animal tests, yet animal welfare groups and chemical manufacturers have appealed many decisions in which the European Chemicals Agency rejected non-animal data the companies sought to submit.

The Environmental Protection Agency soon will invite chemical manufacturers, trade associations, animal welfare advocates, and academic and other scientists to help shape an agency strategy to develop and use the results from non-animal, or "alternative," tests for chemical decision making, said Tala Henry, who directs the risk assessment division of the EPA's Office of Pollution Prevention and Toxics. Keene and Henry were among the speakers at a July 12 Toxicology Forum meeting that discussed the Lautenberg Chemical Safety Act, which amended the Toxic Substances Control Act in 2016.

TSCA's amendments require the EPA to develop a non-animal testing strategy by June 22, 2018, to promote the development and use of new scientifically valid test methods that don't use mammals or other vertebrates. That strategy is part a broader requirement for EPA to reduce and replace the use of animals at a time when more tests may be required.

The EPA is deciding whether to seek public participation through a workshop, releasing a draft concept document, or some other method, Henry said. The agency expects to invite interested parties to provide input in a few months, she said.

Reducing Liability

Harvey Clewell, a senior scientist at ScitoVation, a research institute specializing in cell-based and computational methods as chemical evaluation methods, echoed Keene's point that some European chemical regulators have not used available non-animal test methods.

The U.S., however, has a growing academic, federal and industry scientific infrastructure supporting their development and use, he said. Clewell pointed to federal agencies such the EPA and National Institute of Environmental Health Sciences (NIEHS), which have been developing and using a spectrum of automated chemical testing systems.

Using alternative tests "just makes good sense," especially in the early stages of a new chemical's development, Clewell said. "There's a lot of liability potential for chemicals. They can cost a company a lot of money once they are out there. Wouldn't it behoove a company to run some quick tests and say 'this has red flags why should we pursue it'."

Suzanne Hartigan, director of science policy and regulatory affairs at the International Fragrance Association North America, said fragrance makers already have developed strategies to obtain chemical safety data from alternative tests, so they could comply with the EU's Cosmetics Products Regulation and its predecessor—the Cosmetics Directive—which phased out the use of animal tests on cosmetics and their ingredients.

The Research Institute for Fragrance Materials, Inc., which assesses fragrance safety, has developed a phased in, or "tiered," testing strategy that begins with evaluating existing data for a particular fragrance, proceeds to examining information about similar compounds, and builds toward in vitro and computer-modeled tests, Hartigan said. After such alternative data sources have been utilized, animal tests can be considered, she said, urging EPA to consider some of these strategies.

No Double Standard

Henry said EPA already would review non-animal chemical safety data if companies submitted it but added, "It's not flooding into us."

The more companies submit alternative data, the more it will help the agency understand their uses and limitations, she said.

Richard Denison, lead senior scientist with the Environmental Defense Fund, said that group supports the use of alternative tests. Details about tests used to generate data submitted to the EPA should, however, be made available to build public confidence in the tests' predictions, he said. Protocols used for statutorily required animal tests are publicly available.

Many of the assays the EPA uses for its automated chemical testing program, called ToxCast, and that the NIEHS uses for a similar program called Tox21, are proprietary, Denison said.

Alternative test advocates also should avoid a double standard, Denison said.

There's a tendency for proponents to want to use data from an alternative test if it suggests a chemical would not raise health or environmental concerns, he said. Yet if such tests show a problem, then the proponents argue the tests aren't valid because they don't reflect the "real world," Denison said.

From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 7/26/2017 12:55:03 PM

To: Papineni, Sabitha (S) [SPapineni@dow.com]

CC: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: PMN - Intermediate Testing

Hi Sabitha – I spoke with Nancy Beck, with EPA, and would ask that you either call her Personal Address / Ex. 6 3) or write her briefly summarizing your current test order, the situation, and what you would like to approach the Agency with that might attenuate the need for further testing.

Please let me know what I can do to assist, but I would apprise the team here and then give Nancy a call to discuss next steps – an initial call, followed by a meeting is perhaps a 1, 2 sequence.

Daland

From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 7/19/2017 7:56:11 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: Free

Okay, call when it works for you.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Wednesday, July 19, 2017 3:52 PM

To: Juberg, Daland (DR) < DRJuberg@dow.com>

Subject: RE: Free

Ha! I have pretty much back to back meetings all day today and tomorrow. I think there may be a window Friday..

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273 M: 202-731-9910 beck.nancy@epa.gov

From: Juberg, Daland (DR) [mailto:DRJuberg@dow.com]

Sent: Wednesday, July 19, 2017 2:52 PM **To:** Beck, Nancy <<u>Beck, Nancy@epa.gov</u>>

Subject: Free

I am free all morning tomorrow if a certain time works for you.

From: LIU, ANDREW H [ANDREW.H.LIU@chemours.com]

Sent: 7/18/2017 7:32:39 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: Chat & chew

Sensitivity: Private

 \odot

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Tuesday, July 18, 2017 3:32 PM

To: LIU, ANDREW H < ANDREW.H.LIU@chemours.com>

Subject: Re: Chat & chew

Sensitivity: Private

No worries. I look forward to catching up!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

Beck.Nancy@epa.gov

On Jul 18, 2017, at 3:30 PM, LIU, ANDREW H < ANDREW.H.LIU@chemours.com > wrote:

Alexa has a commitment with friends tomorrow night and can't join us. Maybe next time...

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Tuesday, July 18, 2017 10:07 AM

To: LIU, ANDREW H < ANDREW.H.LIU@chemours.com>

Subject: Re: Chat & chew

Sensitivity: Private

Perfect.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

Beck.Nancy@epa.gov

On Jul 18, 2017, at 9:57 AM, LIU, ANDREW H ANDREW.H.LIU@chemours.com wrote:

Never met a pizza I did not like.

Looks awesome! Reminds me of pies we got in Evanston, when I was a postdoc.

See you there at ~7:30 on Wed. Take care!! From: Beck, Nancy [mailto:Beck.Nancy@epa.gov] Sent: Tuesday, July 18, 2017 9:53 AM To: LIU, ANDREW H < ANDREW.H.LIU@chemours.com> Subject: Re: Chat & chew Sensitivity: Private Ok. Nonresponsive Discussion of Personal Matters / Ex. 6 https://yelp.to/qTKq/RcnpjCRMSE Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP Personal Matters / Ex. 6 Beck.Nancy@epa.gov On Jul 18, 2017, at 9:51 AM, LIU, ANDREW H < ANDREW.H.LIU@chemours.com> wrote: Hi Nancy, I suspected as much. Thanks for making the time and looking forward to chatting I'll ask Alexa. I am flexible with location and like most foods. Would you mind picking the place? Take care! Andy From: Beck, Nancy [mailto:Beck.Nancy@epa.gov] Sent: Tuesday, July 18, 2017 9:45 AM To: LIU, ANDREW H < ANDREW.H.LIU@chemours.com >

Subject: Re: Chat & chew

Sensitivity: Private

Crazy busy but good. Looking forward to catching up. Should we invite Alexa to join us?

Personal Matters / Ex. 6

Nancy.

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP

Personal Address / Ex. 6

Beck.Nancy@epa.gov

On Jul 17, 2017, at 6:49 AM, LIU, ANDREW H < ANDREW.H.LIU@chemours.com > wrote:

Hi Nancy,

How are you doing? Hopefully keeping cool in the heat.

Is Wed evening (7:30) still OK with you?

If so, where would be a good place to meet?

Looking forward to chatting!

Andy

----Original Appointment-----

From: LIU, ANDREW H

Sent: Tuesday, June 06, 2017 9:57 AM **To:** LIU, ANDREW H; Beck, Nancy

Subject: Chat & chew

When: Wednesday, July 19, 2017 7:30 PM-9:30 PM

(UTC-05:00) Eastern Time (US & Canada).

Where: TBD

Sensitivity: Private

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Appointment

From: Juberg, Daland (DR) [DRJuberg@dow.com]

Sent: 1/16/2018 4:49:12 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Accepted: Meeting w/ Daland

Location: DCRoomEast3156/DC-EPA-EAST-OCSPP

Start: 1/17/2018 10:30:00 PM **End**: 1/17/2018 11:00:00 PM

Show Time As: Busy

Recurrence: (none)

Appointment

From: Deziel, Dennis (DR) [DRDeziel@dow.com]

Sent: 1/18/2018 11:23:24 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Accepted: General Location: Elephant and Castle

Start: 1/19/2018 5:15:00 PM **End**: 1/19/2018 6:45:00 PM

Show Time As: Busy

Recurrence: (none)